

US3922088 (Prod: Synexus Clinical Research US, Inc. - Dallas)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:16:35

All time stamps listed in this document are displayed in GMT

US3922088

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

[Participant ID](#)

US3922088

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

US3922088

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:42:26

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Date of Birth (MMM yyyy)	(b) (6) 1957
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 20:42:25

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Date of Informed Consent (*dd MMM yyyy*) 08 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

If reason for screen fail is Other, specify _____

Was this participant screened previously?

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

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 20:42:25

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 20:42:25

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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) 22 Feb 2021 20:42:25

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Condition	VASECETOMY
Start date (dd MMM yyyy)	UN UNK 1996
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 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: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:42:26

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:42 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:42
Height (<i>xxx.x</i>)	64.0 in
Weight (<i>xxx.x</i>)	160.6 lb
BMI (<i>xxx.x</i>)	27.62457 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:42:25

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 20:42:25

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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) 22 Feb 2021 20:42:25

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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) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

What was the date of randomization? (dd MMM yyyy) 08 SEP 2020

What was the participant's randomization number? 112451

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) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

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) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 11:42
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 SEP 2020
Time of assessment (00:00-23:59)	14:19 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 14:19
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

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) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 13:20 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 13:20

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) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	08 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:41 (24 HR)
Collection date and time (derived)	08 SEP 2020 12:41

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Collection date (<i>dd MMM yyyy</i>)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:34	08 SEP 2020 12:34
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

97.0 °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

08 SEP 2020 14:14

PC Open Date & Time

08 SEP 2020 13:40

PC Close Date & Time

08 SEP 2020 16:10

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 98.5 °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	08 SEP 2020 20:16
PC Open Date & Time	08 SEP 2020 17:05
PC Close Date & Time	09 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 19:01

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 20:14

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

98.0 °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

11 SEP 2020 22:47

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

98.5 °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

12 SEP 2020 19:33

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

13 SEP 2020 23:20

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

14 SEP 2020 20:10

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 14:14

PC Open Date & Time

08 SEP 2020 13:40

PC Close Date & Time

08 SEP 2020 16:10

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

08 SEP 2020 20:16

PC Open Date & Time

08 SEP 2020 17:05

PC Close Date & Time

09 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 19:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

10 SEP 2020 20:15

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

11 SEP 2020 22:48

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

12 SEP 2020 19:34

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

13 SEP 2020 23:20

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

14 SEP 2020 20:11

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 14:15
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PC Open Date & Time	08 SEP 2020 13:40
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PC Close Date & Time	08 SEP 2020 16:10
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US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 20:18
PC Open Date & Time	08 SEP 2020 17:05
PC Close Date & Time	09 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 19:02
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 20:15
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 22:49
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:34
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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)

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 23:21
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 20:12
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3922088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3922088

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922088

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922088

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

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

Visit date (dd MMM yyyy)	13 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 10:17
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	12:31 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 12:31
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3922088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

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) 13 OCT 2020

What was the treatment time? (00:00-23:59) 11:59 (24 HR)

Treatment Date and Time (derived) 13 OCT 2020 11:59

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

US3922088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

11:06 (24 HR)

Collection date and time (derived)

13 OCT 2020 11:06

US3922088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:47	13 OCT 2020 10:47
Nasopharyngeal Swab 2	No		

US3922088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

97.6 °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

13 OCT 2020 12:32

PC Open Date & Time

13 OCT 2020 12:19

PC Close Date & Time

13 OCT 2020 14:49

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 97.7 °F

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

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

PC Time Stamp	13 OCT 2020 18:55
PC Open Date & Time	13 OCT 2020 15:44
PC Close Date & Time	14 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 OCT 2020 19:55

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 15 OCT 2020 19:51

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 18:15

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

98.8 °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

17 OCT 2020 16:33

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

18 OCT 2020 19:13

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 07:13

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 12:32

PC Open Date & Time

13 OCT 2020 12:19

PC Close Date & Time

13 OCT 2020 14:49

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

13 OCT 2020 18:51

PC Open Date & Time

13 OCT 2020 15:44

PC Close Date & Time

14 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 19:56

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

15 OCT 2020 19:51

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

16 OCT 2020 18:15

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

17 OCT 2020 16:33

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

18 OCT 2020 19:13

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

20 OCT 2020 07:12

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 12:33
PC Open Date & Time	13 OCT 2020 12:19
PC Close Date & Time	13 OCT 2020 14:49

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 18:52
PC Open Date & Time	13 OCT 2020 15:44
PC Close Date & Time	14 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 19:57
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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)

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 19:52
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

96 of 1856

EAB) (1725)

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 18:16
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 16:34
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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)

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:14
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 ☒

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 07:12
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3922088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3922088

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3922088

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922088

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3922088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

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.

US3922088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	12 NOV 2020
Collection time (<i>00:00-23:59</i>)	09:26 (24 HR)
Collection date and time (derived)	12 NOV 2020 09:26

US3922088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:30

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

15 NOV 2020 14:47:47

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 18:04:32
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 12:47:28
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 08:47:20
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 21:36:00
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

17 DEC 2020 12:55:24

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

24 DEC 2020 22:08:27

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

31 DEC 2020 07:39:30

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

09 JAN 2021 12:19:11

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 11:50:17
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

23 JAN 2021 12:15:03

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

28 JAN 2021 17:03:36

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

05 FEB 2021 12:45:40

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

18 FEB 2021 11:13:31

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

26 FEB 2021 14:18:56

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

07 MAR 2021 21:07:41

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 MAR 2021 22:39:52
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 MAR 2021 06:45:36
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	02 APR 2021 13:31:08
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

08 APR 2021 21:26:48

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 09:29:53

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

23 APR 2021 10:07:18

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

01 MAY 2021 13:11:07

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Patient Cloud Open Date & Time	21 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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Patient Cloud Open Date & Time	25 NOV 2021 00:01
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Patient Cloud Close Date & Time	29 NOV 2021 23:59
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US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Patient Cloud Open Date & Time	23 DEC 2021 00:01
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Patient Cloud Close Date & Time	27 DEC 2021 23:59
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US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Patient Cloud Open Date & Time	13 OCT 2022 00:01
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Patient Cloud Close Date & Time	17 OCT 2022 23:59
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US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Patient Cloud Open Date & Time	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Patient Cloud Open Date & Time	27 OCT 2022 00:01
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Patient Cloud Close Date & Time	31 OCT 2022 23:59
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US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

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

US3922088

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:16:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 22:52:54

US3922088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3922088

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3922088

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3922088

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 11 Mar 2021 22:37:17

Generated On: 10 Jun 2021 10:16:35

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3922088

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 22:37:17

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 13:22:43

Generated On: 10 Jun 2021 10:16:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Apr 2021 13:22:43

Generated On: 10 Jun 2021 10:16:35

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3922088

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Apr 2021 13:22:43

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 APR 2021

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

US3922088

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3922088

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 13:22:43

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3922088

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3922088

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:16:35

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3922088

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

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 16:20:00

Generated On: 10 Jun 2021 10:16:35

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

Visit date (dd MMM yyyy)	02 MAR 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3922088

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 15:58:27

Generated On: 10 Jun 2021 10:16:35

Date of updated informed consent (*dd MMM yyyy*) 02 MAR 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 02 MAR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3922088

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Mar 2021 16:20:00

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	02 MAR 2021
Collection time (<i>00:00-23:59</i>)	14:42 (24 HR)
Collection date and time (derived)	02 MAR 2021 14:42

US3922088

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Mar 2021 16:20:00

Generated On: 10 Jun 2021 10:16:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00 - 23:59)	14:45
Collection Date and Time (derived)	02 MAR 2021 14:45

US3922088

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

AEID

Adverse event

SPARADIC DULL PAIN RIGHT
ELBOW

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)

18 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

14 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

AEID	USA-US212-2021-MRNA-1273-P30 1000007
Adverse event	ADRENAL MASS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	10 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT IS STILL CURRENTLY IN HOSPITAL GETTING ALL TEST DONE POSSIBLE SURGERY. WILL SEND FOR MEDICAL RECORDS.
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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

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

Yes ☒

No ☐

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

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 88

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication R HAND TRIGGER FINGER

Dose per administration 15

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

3 TIMES PER WEEK

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

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US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

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

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Name of Medication MULITVITAMIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU 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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3922088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 20:42:25

Generated On: 10 Jun 2021 10:16:35

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:16:35

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 ☐

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 15 Apr 2021 19:22:43

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US212-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 15 Apr 2021 19:22:43

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US212-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/MAR/2021 11:43
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

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 15 Apr 2021 19:22:43

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US212-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	08/APR/2021 11:29
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

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 15 Apr 2021 19:22:43

Generated On: 10 Jun 2021 10:16:35

SAEID	USA-US212-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JENNIFER
Investigator's Last Name	BASHOUR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/APR/2021 09:24
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

US3922088 (Prod: Synexus Clinical Research US, Inc. - Dallas)

US3922088

Form: Participant Creation

Generated On: 10 Jun 2021 10:16:35

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:10:28
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered 'US3922088'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 16:09:52

US3922088

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:37:46
User entered 'Yes (Y)'	Chana Hines (b) (4)	08 Sep 2020 19:06:09
	(b) (4)	

US3922088

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:37:46
User entered '08 SEP 2020'	RWS_ENDPOINT	08 Sep 2020 16:09:53
	ENDPOINT (b) (4)	

US3922088

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:37:46
User entered 'Clinic (Clinic)'	Chana Hines (b) (4)	08 Sep 2020 19:06:09
	(b) (4)	

US3922088

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'SCRN'	System	08 Sep 2020 19:06:09

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered (b) (6) 1957'	RWS_ENDPOINT	08 Sep 2020 16:09:54
	ENDPOINT (b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered '63'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User entered 'YEARS'	System	08 Sep 2020 19:06:59

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User entered '63'	System	08 Sep 2020 19:07:25

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered 'Male (M)'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered 'I'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered '0'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered '0'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered '0'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered '0'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered '0'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered empty.	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered '0'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:16:35

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:34:36
User entered '0'	Chana Hines (b) (4)	08 Sep 2020 19:06:59
	(b) (4)	

US3922088

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:38
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 08-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:56:45
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 08-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you' answered with 'updated' (Site from DM).	Pauline Jackson (b) (4)	05 Nov 2020 14:59:16
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4)	05 Nov 2020 14:59:12
	(b) (4)	
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 08-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:27:25
User entered '8 Sep 2020'	Chana Hines (b) (4)	08 Sep 2020 19:07:25
	(b) (4)	

US3922088

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User entered 'Sep 2020'	System	08 Sep 2020 19:07:25

US3922088

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User entered '2020'	System	08 Sep 2020 19:07:25

US3922088

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:38
User entered 'Amendment 3 (3)'	Chana Hines (b) (4)	08 Sep 2020 19:07:25
	(b) (4)	

US3922088

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:38
User entered 'Yes (Y)'	Chana Hines (b) (4)	08 Sep 2020 19:07:25
	(b) (4)	

US3922088

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:38
User entered empty.	Chana Hines (b) (4)	08 Sep 2020 19:07:25
	(b) (4)	

US3922088

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:38
User entered empty.	Chana Hines (b) (4)	08 Sep 2020 19:07:25
	(b) (4)	

US3922088

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:38
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 19:07:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Sep 2020 19:07:43
User entered 'No (N)' reason for change: Data Entry Error	Chana Hines (b) (4)	08 Sep 2020 19:07:43
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 19:07:25
User entered empty.	Chana Hines (b) (4)	08 Sep 2020 19:07:25
	(b) (4)	

US3922088

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:38
User entered empty.	RWS_ENDPOINT	08 Sep 2020 16:09:53
	ENDPOINT (b) (4)	

US3922088

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:16:35

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User entered '1'	System	08 Sep 2020 19:07:51

US3922088

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:30
User entered 'Yes (Y)'	Chana Hines (b) (4)	08 Sep 2020 19:07:51
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:16:35

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:25:26
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:43:28
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:45:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:45:38
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 13:44:21
User entered 'hypercholesterolemia'	lynn yauch (b) (4)	11 Sep 2020 13:43:55
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'un UNK 2015'	lynn yauch (b) (4)	11 Sep 2020 13:43:55
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:43:55
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:43:55
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:43:55
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:43:55
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'Jan 2015'	System	11 Sep 2020 13:43:55

US3922088

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered '2015'	System	11 Sep 2020 13:43:55

US3922088

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered empty.	System	11 Sep 2020 13:43:55

US3922088

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered empty.	System	11 Sep 2020 13:43:55

US3922088

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:45:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 13:45:38
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 13:44:23
User entered 'hypothyroidism'	lynn yauch (b) (4)	11 Sep 2020 13:44:10
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'un UNK 2017'	lynn yauch (b) (4)	11 Sep 2020 13:44:10
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:44:10
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:44:10
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:44:10
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:44:10
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'Jan 2017'	System	11 Sep 2020 13:44:10

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered '2017'	System	11 Sep 2020 13:44:10

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered empty.	System	11 Sep 2020 13:44:10

US3922088

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered empty.	System	11 Sep 2020 13:44:10

US3922088

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Trigger finger, LLT: Trigger finger - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 15:00:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 15:00:06
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 00:01:45
User closed query 'Source indicates Trigger Finger Right Hand; please review and reconcile. Ensure that Meloxicam taken for condition is updated as well if this needs to be updated in EDC.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 00:01:43
Query 'Source indicates Trigger Finger Right Hand; please review and reconcile. Ensure that Meloxicam taken for condition is updated as well if this needs to be updated in EDC.' answered with 'corrected ' (Site from CRA).	Lorine Cook (b) (4)	10 Nov 2020 21:12:30
Data point term sent to Coder	System	10 Nov 2020 21:12:21
Coding entries removed.	Lorine Cook (b) (4)	10 Nov 2020 21:12:16
User entered 'R Hand TRIGGER FINGER' reason for change: New Information	Lorine Cook (b) (4)	10 Nov 2020 21:12:16
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:05
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User opened query 'Source indicates Trigger Finger Right Hand; please review and reconcile. Ensure that Meloxicam taken for condition is updated as well if this needs to be updated in EDC.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:26:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Trigger finger, LLT: Trigger finger - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 13:46:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 13:46:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	11 Sep 2020 13:45:24
User entered 'trigger finger'	lynn yauch (b) (4)	11 Sep 2020 13:44:32
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'un UNK 2017'	lynn yauch (b) (4)	11 Sep 2020 13:44:32
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:44:32
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:44:32
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:44:32
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:44:32
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'Jan 2017'	System	11 Sep 2020 13:44:32

US3922088

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered '2017'	System	11 Sep 2020 13:44:32

US3922088

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered empty.	System	11 Sep 2020 13:44:32

US3922088

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered empty.	System	11 Sep 2020 13:44:32

US3922088

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 07:57:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 07:57:42
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 13:45:24
User entered 'vasectomy'	lynn yauch (b) (4)	11 Sep 2020 13:44:56
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'un UNK 1996'	lynn yauch (b) (4)	11 Sep 2020 13:44:56
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:44:56
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:44:56
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'un UNK 1996'	lynn yauch (b) (4)	11 Sep 2020 13:44:56
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:44:56
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'Jan 1996'	System	11 Sep 2020 13:44:56

US3922088

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered '1996'	System	11 Sep 2020 13:44:56

US3922088

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'Jan 1996'	System	11 Sep 2020 13:44:56

US3922088

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered '1996'	System	11 Sep 2020 13:44:56

US3922088

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 16:38:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 16:38:34
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 16:37:39
User entered 'seasonal allergies'	lynn yauch (b) (4)	14 Oct 2020 16:37:01
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'un UNK 2019'	lynn yauch (b) (4)	14 Oct 2020 16:37:01
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered '0'	lynn yauch (b) (4)	14 Oct 2020 16:37:01
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Oct 2020 16:37:01
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered empty.	lynn yauch (b) (4)	14 Oct 2020 16:37:01
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:27:00
User entered '0'	lynn yauch (b) (4)	14 Oct 2020 16:37:01
	(b) (4)	

US3922088

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'Jan 2019'	System	14 Oct 2020 16:37:01

US3922088

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered '2019'	System	14 Oct 2020 16:37:01

US3922088

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered empty.	System	14 Oct 2020 16:37:01

US3922088

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered empty.	System	14 Oct 2020 16:37:01

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered '08 Sep 2020'	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered '11:42'	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered '08 Sep 2020 11:42'	System	11 Sep 2020 13:09:09

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered '64.0' in	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	
DataPoint set to visible.	System	08 Sep 2020 19:07:51

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered '160.6' lb	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	
DataPoint set to visible.	System	08 Sep 2020 19:07:51

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered '27.62457'	System	11 Sep 2020 13:09:09
DataPoint set to visible.	System	08 Sep 2020 19:07:51

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'kg/m2'	System	11 Sep 2020 13:09:09
DataPoint set to visible.	System	08 Sep 2020 19:07:51

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'bpm'	System	11 Sep 2020 13:09:09

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'breaths/min'	System	11 Sep 2020 13:09:09

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'mmHg'	System	11 Sep 2020 13:09:09

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:19
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:09:09
	(b) (4)	

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User entered 'mmHg'	System	11 Sep 2020 13:09:09

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 12:10:32

US3922088

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32

US3922088

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:30:50
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:04:45
	(b) (4)	

US3922088

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:30:50
User entered '08 Sep 2020'	lynn yauch (b) (4)	11 Sep 2020 13:04:45
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

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Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

US3922088

Folder: Screening

Form: Risk of Exposure

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[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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered 'I'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:16:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:10:32
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:29:58
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:06:53
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:02
User entered 'Yes (Y)'	Chana Hines (b) (4)	08 Sep 2020 19:08:16

US3922088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
User closed query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 08-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 11:59:55
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:02
Query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 08-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' answered with 'As per CDM I recorded the date using the correct format.' (Site from DM).	Pamela Echols (b) (4) (b) (4)	05 Nov 2020 16:32:55
User entered '08 Sep 2020' reason for change: Data Entry Error	Pamela Echols (b) (4) (b) (4)	05 Nov 2020 16:30:08
User opened query 'Per CDM: Date format is not correctly recorded. Please review the Date field, it must be 2 digits (dd-MMM-YYYY) format (e.g. 08-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:56:29
User entered '8 Sep 2020'	Chana Hines (b) (4) (b) (4)	08 Sep 2020 19:08:16

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:02
User entered 'Clinic (Clinic)'	Chana Hines (b) (4)	08 Sep 2020 19:08:16

US3922088

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'VISIT1'	System	08 Sep 2020 19:08:16

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:33:38
User entered '08 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 17:34:55

US3922088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:33:38
User entered '112451'	RWS_ENDPOINT	08 Sep 2020 17:34:55
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:33:38
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 17:34:55

US3922088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:33:38
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:38:50

US3922088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:33:38
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:38:50

US3922088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:33:38
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:38:50

US3922088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:33:38
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:38:50

US3922088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:33:38
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:38:50

US3922088

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:16:35

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:33:38
User entered 'No (N)'	Pamela Echols (b) (4)	21 Oct 2020 17:09:09
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:39:06
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:39:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:43:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:43:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User accepted default value 'Pre-Dose (PREDOSE)'	lynn yauch (b) (4) (b) (4)	11 Sep 2020 13:43:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '08 Sep 2020'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '11:42'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '08 Sep 2020 11:42'	System	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '97.7' F	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered 'Oral (Oral)'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '58'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'bpm'	System	11 Sep 2020 13:43:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	11 Nov 2020 00:02:01
User closed query 'Source indicates 15 RR; please review and reconcile as necessary.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 00:02:00
Query 'Source indicates 15 RR; please review and reconcile as necessary.' answered with 'updated ' (Site from CRA).	Lorine Cook (b) (4)	10 Nov 2020 21:03:18
User entered '15' reason for change: Data Entry Error	(b) (4)	(b) (4)
User opened query 'Source indicates 15 RR; please review and reconcile as necessary.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:35:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '13'	lynn yauch (b) (4)	11 Sep 2020 13:43:18
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'breaths/min'	System	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '127'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'mmHg'	System	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '82'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'mmHg'	System	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:16:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered missing code ND - Not Done.	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User accepted default value 'Post-Dose (POSTDOSE)'	lynn yauch (b) (4) (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '08 Sep 2020'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '14:19'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '08 Sep 2020 14:19'	System	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '97.0' F	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered 'Oral (Oral)'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '55'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'bpm'	System	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '13'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'breaths/min'	System	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '133'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'mmHg'	System	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:35:23
User entered '77'	lynn yauch (b) (4)	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'mmHg'	System	11 Sep 2020 13:43:18

US3922088

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:33:11
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:38:58

US3922088

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:33:11
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:38:58

US3922088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:36
User entered 'Yes (Y)'	Chana Hines (b) (4)	08 Sep 2020 19:09:25

US3922088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:36
User entered empty.	Chana Hines (b) (4)	08 Sep 2020 19:09:25

US3922088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:36
User entered empty.	Chana Hines (b) (4)	08 Sep 2020 19:09:25

US3922088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 19:09:25

US3922088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:32:36
User closed query 'Per CDM: Date format is not correctly recorded.Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 08-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:07:22
Query 'Per CDM: Date format is not correctly recorded.Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 08-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' answered with 'date corrected' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 13:44:58
User entered '08 Sep 2020' reason for change: Data Entry Error	Pauline Jackson (b) (4) (b) (4)	27 Oct 2020 13:44:50
User opened query 'Per CDM: Date format is not correctly recorded.Please review the Date field, it must be 2 digits (dd-MMM-yyyy) format (e.g. 08-SEP-2020). Leading zeroes are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:07:54
User entered '8 Sep 2020'	Chana Hines (b) (4) (b) (4)	08 Sep 2020 19:09:25

US3922088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:36
User entered '13:20'	Chana Hines (b) (4)	08 Sep 2020 19:09:25

US3922088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '08 Sep 2020 13:20'	System	27 Oct 2020 13:44:50
User entered '8 Sep 2020 13:20'	System	08 Sep 2020 19:09:25

US3922088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:36
User entered 'Left Arm (LEFT ARM)'	Chana Hines (b) (4)	08 Sep 2020 19:09:25

US3922088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:36
User entered 'ONCE'	System	08 Sep 2020 19:09:25

US3922088

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 19:09:25

US3922088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:10
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:39:47

US3922088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:10
User entered '08 Sep 2020'	lynn yauch (b) (4)	11 Sep 2020 13:39:47

US3922088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:10
User entered '12:41'	lynn yauch (b) (4)	11 Sep 2020 13:39:47

US3922088

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '08 Sep 2020 12:41'	System	11 Sep 2020 13:39:47

US3922088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:18
User entered '08 Sep 2020'	lynn yauch (b) (4)	11 Sep 2020 13:40:14

US3922088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	lynn yauch (b) (4)	11 Sep 2020 13:40:14

US3922088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:18
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:40:14

US3922088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:18
User entered '12:34'	lynn yauch (b) (4)	11 Sep 2020 13:40:14

US3922088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '08 Sep 2020 12:34'	System	11 Sep 2020 13:40:14

US3922088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	lynn yauch (b) (4)	11 Sep 2020 13:40:14

US3922088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:18
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:40:14

US3922088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:32:18
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:40:14

US3922088

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered empty.	System	11 Sep 2020 13:40:14

US3922088

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:33:16
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:40:22

US3922088

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '1'	System	11 Sep 2020 13:40:22

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:13:36', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e7095be4-e532-49bc-9894-3afd91203152'	System	08 Sep 2020 19:14:08
User entered 'Yes (Y)'	System	08 Sep 2020 19:14:08

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:13:44', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e7095be4-e532-49bc-9894-3afd91203152'	System	08 Sep 2020 19:14:08
User entered '97.0'	System	08 Sep 2020 19:14:08

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:13:54', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e7095be4-e532-49bc-9894-3afd91203152'	System	08 Sep 2020 19:14:08
User entered 'No (N)'	System	08 Sep 2020 19:14:08

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:14:05', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e7095be4-e532-49bc-9894-3afd91203152'	System	08 Sep 2020 19:14:08
User entered '08 Sep 2020 14:14'	System	08 Sep 2020 19:14:08

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '08 Sep 2020 13:40'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '08 Sep 2020 16:10'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:15:39', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '3c4e2cc4-9457-4809-be49-ded57c643765' User entered 'Yes (Y)'	System	09 Sep 2020 01:16:08
	System	09 Sep 2020 01:16:08

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:15:48', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '3c4e2cc4-9457-4809-be49-ded57c643765' User entered '98.5'	System	09 Sep 2020 01:16:08
	System	09 Sep 2020 01:16:08

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:15:54', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '3c4e2cc4-9457-4809-be49-ded57c643765' User entered 'No (N)'	System	09 Sep 2020 01:16:08
	System	09 Sep 2020 01:16:08

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:16:02', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '3c4e2cc4-9457-4809-be49-ded57c643765'	System	09 Sep 2020 01:16:08
User entered '08 Sep 2020 20:16'	System	09 Sep 2020 01:16:08

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '08 Sep 2020 17:05'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 2'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:01:21', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a5ca059-0ba4-4d26-882c-296bf4276fa7'	System	10 Sep 2020 00:01:40
User entered 'Yes (Y)'	System	10 Sep 2020 00:01:40

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:01:27', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a5ca059-0ba4-4d26-882c-296bf4276fa7'	System	10 Sep 2020 00:01:40
User entered '98.7'	System	10 Sep 2020 00:01:40

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:01:33', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a5ca059-0ba4-4d26-882c-296bf4276fa7'	System	10 Sep 2020 00:01:40
User entered 'No (N)'	System	10 Sep 2020 00:01:40

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:01:39', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a5ca059-0ba4-4d26-882c-296bf4276fa7'	System	10 Sep 2020 00:01:40
User entered '09 Sep 2020 19:01'	System	10 Sep 2020 00:01:40

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 3'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:14:16', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5bb69bf0-4e09-4bac-9504-5431c0f91437'	System	11 Sep 2020 01:14:30
User entered 'Yes (Y)'	System	11 Sep 2020 01:14:30

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:14:20', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5bb69bf0-4e09-4bac-9504-5431c0f91437' User entered '98.4'	System	11 Sep 2020 01:14:30
	System	11 Sep 2020 01:14:30

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:14:24', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5bb69bf0-4e09-4bac-9504-5431c0f91437'	System	11 Sep 2020 01:14:30
User entered 'No (N)'	System	11 Sep 2020 01:14:30

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:14:28', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5bb69bf0-4e09-4bac-9504-5431c0f91437'	System	11 Sep 2020 01:14:30
User entered '10 Sep 2020 20:14'	System	11 Sep 2020 01:14:30

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 4'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:47:47', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ef000190-324c-4c07-87c8-019057e301ba' User entered 'Yes (Y)'	System	12 Sep 2020 03:47:55
	System	12 Sep 2020 03:47:55

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:47:38', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ef000190-324c-4c07-87c8-019057e301ba' User entered '98.0'	System	12 Sep 2020 03:47:55
	System	12 Sep 2020 03:47:55

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:47:43', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ef000190-324c-4c07-87c8-019057e301ba' User entered 'No (N)'	System	12 Sep 2020 03:47:55
	System	12 Sep 2020 03:47:55

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:47:53', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ef000190-324c-4c07-87c8-019057e301ba' User entered '11 Sep 2020 22:47'	System	12 Sep 2020 03:47:55
	System	12 Sep 2020 03:47:55

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 5'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:33:26', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '375331e9-3e97-4c43-8e38-1859db639a2b' User entered 'Yes (Y)'	System	13 Sep 2020 00:33:40
	System	13 Sep 2020 00:33:40

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:33:31', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '375331e9-3e97-4c43-8e38-1859db639a2b' User entered '98.5'	System	13 Sep 2020 00:33:40
	System	13 Sep 2020 00:33:40

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:33:34', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '375331e9-3e97-4c43-8e38-1859db639a2b' User entered 'No (N)'	System	13 Sep 2020 00:33:40
	System	13 Sep 2020 00:33:40

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:33:38', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '375331e9-3e97-4c43-8e38-1859db639a2b' User entered '12 Sep 2020 19:33'	System	13 Sep 2020 00:33:40
	System	13 Sep 2020 00:33:40

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 6'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:19:57', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fb68898-dd25-4705-b587-4e70540e32b0'	System	14 Sep 2020 04:20:16
User entered 'Yes (Y)'	System	14 Sep 2020 04:20:16

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fb68898-dd25-4705-b587-4e70540e32b0' User entered '97.3'	System	14 Sep 2020 04:20:16
	System	14 Sep 2020 04:20:16

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:07', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fb68898-dd25-4705-b587-4e70540e32b0'	System	14 Sep 2020 04:20:16
User entered 'No (N)'	System	14 Sep 2020 04:20:16

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:11', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fb68898-dd25-4705-b587-4e70540e32b0'	System	14 Sep 2020 04:20:16
User entered '13 Sep 2020 23:20'	System	14 Sep 2020 04:20:16

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 7'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:10:42', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ae66f6c3-d8ac-4fbe-8996-0fca3e748406' User entered 'Yes (Y)'	System	15 Sep 2020 01:11:06
	System	15 Sep 2020 01:11:06

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:10:49', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ae66f6c3-d8ac-4fbe-8996-0fca3e748406' User entered '98.1'	System	15 Sep 2020 01:11:06
	System	15 Sep 2020 01:11:06

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:10:54', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ae66f6c3-d8ac-4fbe-8996-0fca3e748406'	System	15 Sep 2020 01:11:06
User entered 'No (N)'	System	15 Sep 2020 01:11:06

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:10:59', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ae66f6c3-d8ac-4fbe-8996-0fca3e748406' User entered '14 Sep 2020 20:10'	System	15 Sep 2020 01:11:06
	System	15 Sep 2020 01:11:06

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:14:17', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2153d8e1-9000-4af4-86db-4075365e0efa' User entered 'None (1)'	System	08 Sep 2020 19:14:57
	System	08 Sep 2020 19:14:57

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:14:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2153d8e1-9000-4af4-86db-4075365e0efa' User entered 'No (N)'	System	08 Sep 2020 19:14:57
	System	08 Sep 2020 19:14:57

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:14:41', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2153d8e1-9000-4af4-86db-4075365e0efa' User entered 'No (N)'	System	08 Sep 2020 19:14:57
	System	08 Sep 2020 19:14:57

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:14:48', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2153d8e1-9000-4af4-86db-4075365e0efa' User entered 'None (1)'	System	08 Sep 2020 19:14:57
	System	08 Sep 2020 19:14:57

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:14:53', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2153d8e1-9000-4af4-86db-4075365e0efa' User entered '08 Sep 2020 14:14'	System	08 Sep 2020 19:14:57
	System	08 Sep 2020 19:14:57

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '08 Sep 2020 13:40'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '08 Sep 2020 16:10'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:16:13', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '3c090a28-665b-4a40-9f11-a9ca0762f571' User entered 'None (1)'	System	09 Sep 2020 01:16:34
	System	09 Sep 2020 01:16:34

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:16:18', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '3c090a28-665b-4a40-9f11-a9ca0762f571' User entered 'No (N)'	System	09 Sep 2020 01:16:34
	System	09 Sep 2020 01:16:34

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:16:24', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '3c090a28-665b-4a40-9f11-a9ca0762f571' User entered 'No (N)'	System	09 Sep 2020 01:16:34
	System	09 Sep 2020 01:16:34

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:16:28', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '3c090a28-665b-4a40-9f11-a9ca0762f571' User entered 'None (1)'	System	09 Sep 2020 01:16:34
	System	09 Sep 2020 01:16:34

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:16:32', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '3c090a28-665b-4a40-9f11-a9ca0762f571' User entered '08 Sep 2020 20:16'	System	09 Sep 2020 01:16:34
	System	09 Sep 2020 01:16:34

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '08 Sep 2020 17:05'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 2'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:01:53', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '20031087-6415-4d7d-b2ec-aa093090e91d'	System	10 Sep 2020 00:02:11
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 00:02:11

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:01:56', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '20031087-6415-4d7d-b2ec-aa093090e91d'	System	10 Sep 2020 00:02:11
User entered 'No (N)'	System	10 Sep 2020 00:02:11

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '20031087-6415-4d7d-b2ec-aa093090e91d' User entered 'No (N)'	System	10 Sep 2020 00:02:11
	System	10 Sep 2020 00:02:11

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '20031087-6415-4d7d-b2ec-aa093090e91d'	System	10 Sep 2020 00:02:11
User entered 'None (1)'	System	10 Sep 2020 00:02:11

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:09', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '20031087-6415-4d7d-b2ec-aa093090e91d' User entered '09 Sep 2020 19:02'	System	10 Sep 2020 00:02:11
	System	10 Sep 2020 00:02:11

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 3'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:14:40', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f8d71af5-d9d8-4b25-9179-fb3dba0ba327'	System	11 Sep 2020 01:15:10
User entered 'None (1)'	System	11 Sep 2020 01:15:10

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:14:43', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f8d71af5-d9d8-4b25-9179-fb3dba0ba327'	System	11 Sep 2020 01:15:10
User entered 'No (N)'	System	11 Sep 2020 01:15:10

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:14:47', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f8d71af5-d9d8-4b25-9179-fb3dba0ba327'	System	11 Sep 2020 01:15:10
User entered 'No (N)'	System	11 Sep 2020 01:15:10

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:15:01', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f8d71af5-d9d8-4b25-9179-fb3dba0ba327'	System	11 Sep 2020 01:15:10
User entered 'None (1)'	System	11 Sep 2020 01:15:10

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:15:06', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f8d71af5-d9d8-4b25-9179-fb3dba0ba327'	System	11 Sep 2020 01:15:10
User entered '10 Sep 2020 20:15'	System	11 Sep 2020 01:15:10

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 4'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:48:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7bc354d6-0473-40e0-b7a8-86f76ad53bbc' User entered 'None (1)'	System	12 Sep 2020 03:48:31
	System	12 Sep 2020 03:48:31

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:48:06', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7bc354d6-0473-40e0-b7a8-86f76ad53bbc' User entered 'No (N)'	System	12 Sep 2020 03:48:31
	System	12 Sep 2020 03:48:31

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:48:20', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7bc354d6-0473-40e0-b7a8-86f76ad53bbc' User entered 'No (N)'	System	12 Sep 2020 03:48:31
	System	12 Sep 2020 03:48:31

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:48:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7bc354d6-0473-40e0-b7a8-86f76ad53bbc'	System	12 Sep 2020 03:48:31
User entered 'None (1)'	System	12 Sep 2020 03:48:31

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:48:28', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7bc354d6-0473-40e0-b7a8-86f76ad53bbc'	System	12 Sep 2020 03:48:31
User entered '11 Sep 2020 22:48'	System	12 Sep 2020 03:48:31

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 5'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:33:48', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5b1d473d-f2fd-4ac8-8688-5297900501ee' User entered 'None (1)'	System	13 Sep 2020 00:34:07
	System	13 Sep 2020 00:34:07

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:33:51', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5b1d473d-f2fd-4ac8-8688-5297900501ee' User entered 'No (N)'	System	13 Sep 2020 00:34:07
	System	13 Sep 2020 00:34:07

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:33:55', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5b1d473d-f2fd-4ac8-8688-5297900501ee' User entered 'No (N)'	System	13 Sep 2020 00:34:07
	System	13 Sep 2020 00:34:07

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:33:59', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5b1d473d-f2fd-4ac8-8688-5297900501ee' User entered 'None (1)'	System	13 Sep 2020 00:34:07
	System	13 Sep 2020 00:34:07

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:34:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5b1d473d-f2fd-4ac8-8688-5297900501ee' User entered '12 Sep 2020 19:34'	System	13 Sep 2020 00:34:07
	System	13 Sep 2020 00:34:07

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 6'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:18', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '059c1175-f18e-47ae-b1d5-3859b76a1e92'	System	14 Sep 2020 04:20:42
User entered 'None (1)'	System	14 Sep 2020 04:20:42

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '059c1175-f18e-47ae-b1d5-3859b76a1e92'	System	14 Sep 2020 04:20:42
User entered 'No (N)'	System	14 Sep 2020 04:20:42

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:27', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '059c1175-f18e-47ae-b1d5-3859b76a1e92'	System	14 Sep 2020 04:20:42
User entered 'No (N)'	System	14 Sep 2020 04:20:42

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:33', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '059c1175-f18e-47ae-b1d5-3859b76a1e92'	System	14 Sep 2020 04:20:42
User entered 'None (1)'	System	14 Sep 2020 04:20:42

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:36', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '059c1175-f18e-47ae-b1d5-3859b76a1e92'	System	14 Sep 2020 04:20:42
User entered '13 Sep 2020 23:20'	System	14 Sep 2020 04:20:42

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 7'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:05', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'd0b34eff-3d8a-4b98-8972-499bb0b1b5f4'	System	15 Sep 2020 01:11:28
User entered 'None (1)'	System	15 Sep 2020 01:11:28

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:10', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'd0b34eff-3d8a-4b98-8972-499bb0b1b5f4'	System	15 Sep 2020 01:11:28
User entered 'No (N)'	System	15 Sep 2020 01:11:28

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:14', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'd0b34eff-3d8a-4b98-8972-499bb0b1b5f4' User entered 'No (N)'	System	15 Sep 2020 01:11:28
	System	15 Sep 2020 01:11:28

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:17', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'd0b34eff-3d8a-4b98-8972-499bb0b1b5f4'	System	15 Sep 2020 01:11:28
User entered 'None (1)'	System	15 Sep 2020 01:11:28

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:24', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'd0b34eff-3d8a-4b98-8972-499bb0b1b5f4'	System	15 Sep 2020 01:11:28
User entered '14 Sep 2020 20:11'	System	15 Sep 2020 01:11:28

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:14:58', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2c37f81b-b33f-48bb-9f42-71d4a8133a15' User entered 'None (0)'	System	08 Sep 2020 19:15:30
	System	08 Sep 2020 19:15:30

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:15:02', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2c37f81b-b33f-48bb-9f42-71d4a8133a15' User entered 'None (0)'	System	08 Sep 2020 19:15:30
	System	08 Sep 2020 19:15:30

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:15:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2c37f81b-b33f-48bb-9f42-71d4a8133a15' User entered 'None (0)'	System	08 Sep 2020 19:15:30
	System	08 Sep 2020 19:15:30

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:15:12', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2c37f81b-b33f-48bb-9f42-71d4a8133a15' User entered 'None (0)'	System	08 Sep 2020 19:15:30
	System	08 Sep 2020 19:15:30

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:15:15', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2c37f81b-b33f-48bb-9f42-71d4a8133a15' User entered 'None (0)'	System	08 Sep 2020 19:15:30
	System	08 Sep 2020 19:15:30

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:15:18', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2c37f81b-b33f-48bb-9f42-71d4a8133a15' User entered 'None (0)'	System	08 Sep 2020 19:15:30
	System	08 Sep 2020 19:15:30

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:15:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2c37f81b-b33f-48bb-9f42-71d4a8133a15' User entered 'No (N)'	System	08 Sep 2020 19:15:30
	System	08 Sep 2020 19:15:30

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T14:15:27', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2c37f81b-b33f-48bb-9f42-71d4a8133a15' User entered '08 Sep 2020 14:15'	System	08 Sep 2020 19:15:30
	System	08 Sep 2020 19:15:30

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '08 Sep 2020 13:40'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '08 Sep 2020 16:10'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:16:43', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7f0f9e2a-b44f-4e1e-8a01-18d1653a27dd'	System	09 Sep 2020 01:18:25
User entered 'None (0)'	System	09 Sep 2020 01:18:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:16:51', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7f0f9e2a-b44f-4e1e-8a01-18d1653a27dd' User entered 'None (0)'	System	09 Sep 2020 01:18:25
	System	09 Sep 2020 01:18:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:16:57', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7f0f9e2a-b44f-4e1e-8a01-18d1653a27dd' User entered 'None (0)'	System	09 Sep 2020 01:18:25
	System	09 Sep 2020 01:18:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:17:58', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7f0f9e2a-b44f-4e1e-8a01-18d1653a27dd' User entered 'None (0)'	System	09 Sep 2020 01:18:25
	System	09 Sep 2020 01:18:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:18:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7f0f9e2a-b44f-4e1e-8a01-18d1653a27dd' User entered 'None (0)'	System	09 Sep 2020 01:18:25
	System	09 Sep 2020 01:18:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:18:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7f0f9e2a-b44f-4e1e-8a01-18d1653a27dd' User entered 'None (0)'	System	09 Sep 2020 01:18:25
	System	09 Sep 2020 01:18:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:18:13', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7f0f9e2a-b44f-4e1e-8a01-18d1653a27dd'	System	09 Sep 2020 01:18:25
User entered 'No (N)'	System	09 Sep 2020 01:18:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-08T20:18:20', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7f0f9e2a-b44f-4e1e-8a01-18d1653a27dd' User entered '08 Sep 2020 20:18'	System	09 Sep 2020 01:18:25
	System	09 Sep 2020 01:18:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '08 Sep 2020 17:05'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 2'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:16', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e16be486-6bed-49ac-ae05-6b438c9b7880' User entered 'None (0)'	System	10 Sep 2020 00:02:57
	System	10 Sep 2020 00:02:57

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:18', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e16be486-6bed-49ac-ae05-6b438c9b7880' User entered 'None (0)'	System	10 Sep 2020 00:02:57
	System	10 Sep 2020 00:02:57

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:24', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e16be486-6bed-49ac-ae05-6b438c9b7880' User entered 'None (0)'	System	10 Sep 2020 00:02:57
	System	10 Sep 2020 00:02:57

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:30', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e16be486-6bed-49ac-ae05-6b438c9b7880' User entered 'None (0)'	System	10 Sep 2020 00:02:57
	System	10 Sep 2020 00:02:57

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:32', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e16be486-6bed-49ac-ae05-6b438c9b7880' User entered 'None (0)'	System	10 Sep 2020 00:02:57
	System	10 Sep 2020 00:02:57

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:35', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e16be486-6bed-49ac-ae05-6b438c9b7880' User entered 'None (0)'	System	10 Sep 2020 00:02:57
	System	10 Sep 2020 00:02:57

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:47', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e16be486-6bed-49ac-ae05-6b438c9b7880' User entered 'No (N)'	System	10 Sep 2020 00:02:57
	System	10 Sep 2020 00:02:57

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-09T19:02:54', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e16be486-6bed-49ac-ae05-6b438c9b7880' User entered '09 Sep 2020 19:02'	System	10 Sep 2020 00:02:57
	System	10 Sep 2020 00:02:57

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 3'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:15:10', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '45bd83ae-b3f4-4048-8053-38b527b0d80c' User entered 'None (0)'	System	11 Sep 2020 01:15:39
	System	11 Sep 2020 01:15:39

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:15:13', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '45bd83ae-b3f4-4048-8053-38b527b0d80c' User entered 'None (0)'	System	11 Sep 2020 01:15:39
	System	11 Sep 2020 01:15:39

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:15:16', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '45bd83ae-b3f4-4048-8053-38b527b0d80c' User entered 'None (0)'	System	11 Sep 2020 01:15:39
	System	11 Sep 2020 01:15:39

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:15:19', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '45bd83ae-b3f4-4048-8053-38b527b0d80c' User entered 'None (0)'	System	11 Sep 2020 01:15:39
	System	11 Sep 2020 01:15:39

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:15:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '45bd83ae-b3f4-4048-8053-38b527b0d80c' User entered 'None (0)'	System	11 Sep 2020 01:15:39
	System	11 Sep 2020 01:15:39

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:15:25', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '45bd83ae-b3f4-4048-8053-38b527b0d80c' User entered 'None (0)'	System	11 Sep 2020 01:15:39
	System	11 Sep 2020 01:15:39

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:15:28', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '45bd83ae-b3f4-4048-8053-38b527b0d80c' User entered 'No (N)'	System	11 Sep 2020 01:15:39
	System	11 Sep 2020 01:15:39

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-10T20:15:36', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '45bd83ae-b3f4-4048-8053-38b527b0d80c' User entered '10 Sep 2020 20:15'	System	11 Sep 2020 01:15:39
	System	11 Sep 2020 01:15:39

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 4'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:48:33', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '1f3dcd6f-d7e5-42eb-8207-efa62e634767'	System	12 Sep 2020 03:49:21
User entered 'None (0)'	System	12 Sep 2020 03:49:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:48:43', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '1f3dcd6f-d7e5-42eb-8207-efa62e634767' User entered 'None (0)'	System	12 Sep 2020 03:49:21
	System	12 Sep 2020 03:49:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:48:55', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '1f3dcd6f-d7e5-42eb-8207-efa62e634767' User entered 'None (0)'	System	12 Sep 2020 03:49:21
	System	12 Sep 2020 03:49:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:49:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '1f3dcd6f-d7e5-42eb-8207-efa62e634767' User entered 'None (0)'	System	12 Sep 2020 03:49:21
	System	12 Sep 2020 03:49:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:49:05', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '1f3dcd6f-d7e5-42eb-8207-efa62e634767' User entered 'None (0)'	System	12 Sep 2020 03:49:21
	System	12 Sep 2020 03:49:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:49:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '1f3dcd6f-d7e5-42eb-8207-efa62e634767' User entered 'None (0)'	System	12 Sep 2020 03:49:21
	System	12 Sep 2020 03:49:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:49:12', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '1f3dcd6f-d7e5-42eb-8207-efa62e634767'	System	12 Sep 2020 03:49:21
User entered 'No (N)'	System	12 Sep 2020 03:49:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-11T22:49:17', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '1f3dcd6f-d7e5-42eb-8207-efa62e634767'	System	12 Sep 2020 03:49:21
User entered '11 Sep 2020 22:49'	System	12 Sep 2020 03:49:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 5'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:34:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0665a0c-081e-4625-9677-52b93de03c09' User entered 'None (0)'	System	13 Sep 2020 00:34:59
	System	13 Sep 2020 00:34:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:34:11', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0665a0c-081e-4625-9677-52b93de03c09' User entered 'None (0)'	System	13 Sep 2020 00:34:59
	System	13 Sep 2020 00:34:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:34:21', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0665a0c-081e-4625-9677-52b93de03c09' User entered 'None (0)'	System	13 Sep 2020 00:34:59
	System	13 Sep 2020 00:34:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:34:31', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0665a0c-081e-4625-9677-52b93de03c09'	System	13 Sep 2020 00:34:59
User entered 'No interference with activity (1)'	System	13 Sep 2020 00:34:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:34:34', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0665a0c-081e-4625-9677-52b93de03c09' User entered 'None (0)'	System	13 Sep 2020 00:34:59
	System	13 Sep 2020 00:34:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:34:37', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0665a0c-081e-4625-9677-52b93de03c09' User entered 'None (0)'	System	13 Sep 2020 00:34:59
	System	13 Sep 2020 00:34:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:34:50', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0665a0c-081e-4625-9677-52b93de03c09' User entered 'No (N)'	System	13 Sep 2020 00:34:59
	System	13 Sep 2020 00:34:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-12T19:34:56', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0665a0c-081e-4625-9677-52b93de03c09' User entered '12 Sep 2020 19:34'	System	13 Sep 2020 00:34:59
	System	13 Sep 2020 00:34:59

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 6'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:42', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a295965-53ac-4b95-92f5-b489175df927' User entered 'None (0)'	System	14 Sep 2020 04:21:21
	System	14 Sep 2020 04:21:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:45', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a295965-53ac-4b95-92f5-b489175df927' User entered 'None (0)'	System	14 Sep 2020 04:21:21
	System	14 Sep 2020 04:21:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:20:54', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a295965-53ac-4b95-92f5-b489175df927' User entered 'None (0)'	System	14 Sep 2020 04:21:21
	System	14 Sep 2020 04:21:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:21:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a295965-53ac-4b95-92f5-b489175df927' User entered 'None (0)'	System	14 Sep 2020 04:21:21
	System	14 Sep 2020 04:21:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:21:06', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a295965-53ac-4b95-92f5-b489175df927' User entered 'None (0)'	System	14 Sep 2020 04:21:21
	System	14 Sep 2020 04:21:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:21:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a295965-53ac-4b95-92f5-b489175df927' User entered 'None (0)'	System	14 Sep 2020 04:21:21
	System	14 Sep 2020 04:21:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:21:13', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a295965-53ac-4b95-92f5-b489175df927'	System	14 Sep 2020 04:21:21
User entered 'No (N)'	System	14 Sep 2020 04:21:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-13T23:21:19', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7a295965-53ac-4b95-92f5-b489175df927'	System	14 Sep 2020 04:21:21
User entered '13 Sep 2020 23:21'	System	14 Sep 2020 04:21:21

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 7'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:35', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e13f4fd2-766b-46cb-9a2d-666c64bbd183' User entered 'None (0)'	System	15 Sep 2020 01:12:12
	System	15 Sep 2020 01:12:12

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:37', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e13f4fd2-766b-46cb-9a2d-666c64bbd183' User entered 'None (0)'	System	15 Sep 2020 01:12:12
	System	15 Sep 2020 01:12:12

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:41', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e13f4fd2-766b-46cb-9a2d-666c64bbd183' User entered 'None (0)'	System	15 Sep 2020 01:12:12
	System	15 Sep 2020 01:12:12

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:45', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e13f4fd2-766b-46cb-9a2d-666c64bbd183' User entered 'None (0)'	System	15 Sep 2020 01:12:12
	System	15 Sep 2020 01:12:12

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:46', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e13f4fd2-766b-46cb-9a2d-666c64bbd183' User entered 'None (0)'	System	15 Sep 2020 01:12:12
	System	15 Sep 2020 01:12:12

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:11:49', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e13f4fd2-766b-46cb-9a2d-666c64bbd183' User entered 'None (0)'	System	15 Sep 2020 01:12:12
	System	15 Sep 2020 01:12:12

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:12:01', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e13f4fd2-766b-46cb-9a2d-666c64bbd183'	System	15 Sep 2020 01:12:12
User entered 'No (N)'	System	15 Sep 2020 01:12:12

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-09-14T20:12:07', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e13f4fd2-766b-46cb-9a2d-666c64bbd183'	System	15 Sep 2020 01:12:12
User entered '14 Sep 2020 20:12'	System	15 Sep 2020 01:12:12

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 19:09:25

US3922088

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:15
User entered 'Yes (Y)'	Lorine Cook (b) (4)	16 Sep 2020 00:04:28

US3922088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:15
User entered '15 Sep 2020'	Lorine Cook (b) (4)	16 Sep 2020 00:04:28

US3922088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:15
User entered 'Contact Made (CONTACT MADE)'	Lorine Cook (b) (4)	16 Sep 2020 00:04:28

US3922088

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:15
User entered empty.	Lorine Cook (b) (4)	16 Sep 2020 00:04:28

US3922088

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:32
User entered 'Yes (Y)'	Lorine Cook (b) (4)	16 Sep 2020 00:04:35

US3922088

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'I'	System	16 Sep 2020 00:04:35

US3922088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:38
User entered 'Yes (Y)'	Chana Hines (b) (4)	22 Sep 2020 23:34:08

US3922088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:38
User entered '22 Sep 2020'	Chana Hines (b) (4)	22 Sep 2020 23:34:08

US3922088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:38
User entered 'Contact Made (CONTACT MADE)'	Chana Hines (b) (4)	22 Sep 2020 23:34:08

US3922088

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:38
User entered empty.	Chana Hines (b) (4)	22 Sep 2020 23:34:08

US3922088

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:42
User entered 'Yes (Y)'	Chana Hines (b) (4)	22 Sep 2020 23:34:15

US3922088

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'I'	System	22 Sep 2020 23:34:15

US3922088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:39:04
User entered 'Yes (Y)'	Chana Hines (b) (4)	29 Sep 2020 18:49:19

US3922088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:39:04
User entered '29 Sep 2020'	Chana Hines (b) (4)	29 Sep 2020 18:49:19

US3922088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:39:04
User entered 'Contact Made (CONTACT MADE)'	Chana Hines (b) (4)	29 Sep 2020 18:49:19

US3922088

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:39:04
User entered empty.	Chana Hines (b) (4)	29 Sep 2020 18:49:19

US3922088

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:39:28
User entered 'Yes (Y)'	Chana Hines (b) (4)	29 Sep 2020 18:49:25

US3922088

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'I'	System	29 Sep 2020 18:49:25

US3922088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:09:53
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	13 Oct 2020 17:11:05

US3922088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:09:53
User entered '13 Oct 2020'	Patrick Brooks (b) (4)	13 Oct 2020 17:11:05

US3922088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:09:53
User entered 'Clinic (Clinic)'	Patrick Brooks (b) (4)	13 Oct 2020 17:11:05

US3922088

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'VISIT2'	System	13 Oct 2020 17:11:05

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User accepted default value 'Pre-Dose (PREDOSE)'	lynn yauch (b) (4)	14 Oct 2020 16:35:52
	(b) (4)	

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '13 Oct 2020'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '10:17'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '13 Oct 2020 10:17'	System	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '98.6' F	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered 'Oral (Oral)'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered empty.	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '66'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'bpm'	System	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '16'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'breaths/min'	System	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '135'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'mmHg'	System	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '84'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'mmHg'	System	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User accepted default value 'Post-Dose (POSTDOSE)'	lynn yauch (b) (4) (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '13 Oct 2020'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '12:31'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '13 Oct 2020 12:31'	System	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '97.6' F	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered 'Oral (Oral)'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered empty.	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '61'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'bpm'	System	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '16'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'breaths/min'	System	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '131'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'mmHg'	System	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:39
User entered '86'	lynn yauch (b) (4)	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'mmHg'	System	14 Oct 2020 16:35:52

US3922088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:58
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Oct 2020 16:37:13

US3922088

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:49:58
User entered '13 Oct 2020'	lynn yauch (b) (4)	14 Oct 2020 16:37:13

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:08
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	13 Oct 2020 17:11:41

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:08
User entered empty.	Patrick Brooks (b) (4)	13 Oct 2020 17:11:41

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:08
User entered empty.	Patrick Brooks (b) (4)	13 Oct 2020 17:11:41

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 17:11:41

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:08
User entered '13 Oct 2020'	Patrick Brooks (b) (4)	13 Oct 2020 17:11:41

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:08
User entered '11:59'	Patrick Brooks (b) (4)	13 Oct 2020 17:11:41

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '13 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:08
User entered 'Left Arm (LEFT ARM)'	Patrick Brooks (b) (4)	13 Oct 2020 17:11:41

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:08
User entered 'ONCE'	System	13 Oct 2020 17:11:41

US3922088

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:16:35

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 17:11:41

US3922088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:43
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Oct 2020 16:34:33

US3922088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:43
User entered '13 Oct 2020'	lynn yauch (b) (4)	14 Oct 2020 16:34:33

US3922088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:43
User entered '11:06'	lynn yauch (b) (4)	14 Oct 2020 16:34:33

US3922088

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '13 Oct 2020 11:06'	System	14 Oct 2020 16:34:33

US3922088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:16:35

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:53
User entered '13 Oct 2020'	lynn yauch (b) (4)	14 Oct 2020 16:34:50

US3922088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	lynn yauch (b) (4)	14 Oct 2020 16:34:50

US3922088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:53
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Oct 2020 16:34:50

US3922088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:53
User entered '10:47'	lynn yauch (b) (4)	14 Oct 2020 16:34:50

US3922088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '13 Oct 2020 10:47'	System	14 Oct 2020 16:34:50

US3922088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	lynn yauch (b) (4)	14 Oct 2020 16:34:50

US3922088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:53
User entered 'No (N)'	lynn yauch (b) (4)	14 Oct 2020 16:34:50

US3922088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:50:53
User entered empty.	lynn yauch (b) (4)	14 Oct 2020 16:34:50

US3922088

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered empty.	System	14 Oct 2020 16:34:50

US3922088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:51:05
User entered 'Yes (Y)'	Patrick Brooks (b) (4)	13 Oct 2020 17:16:37

US3922088

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'I'	System	13 Oct 2020 17:16:37

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:32:07', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0cf6e955-bb8e-43f9-a8a0-c1493f6fea8d' User entered 'Yes (Y)'	System	13 Oct 2020 17:32:38
	System	13 Oct 2020 17:32:38

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:32:13', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0cf6e955-bb8e-43f9-a8a0-c1493f6fea8d' User entered '97.6'	System	13 Oct 2020 17:32:38
	System	13 Oct 2020 17:32:38

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:32:19', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0cf6e955-bb8e-43f9-a8a0-c1493f6fea8d'	System	13 Oct 2020 17:32:38
User entered 'No (N)'	System	13 Oct 2020 17:32:38

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:32:35', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0cf6e955-bb8e-43f9-a8a0-c1493f6fea8d'	System	13 Oct 2020 17:32:38
User entered '13 Oct 2020 12:32'	System	13 Oct 2020 17:32:38

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Oct 2020 12:19'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Oct 2020 14:49'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:54:53', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c218f6f5-ddc5-40f0-bb1c-afe730b41fee' User entered 'Yes (Y)'	System	13 Oct 2020 23:55:12
	System	13 Oct 2020 23:55:12

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:54:57', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c218f6f5-ddc5-40f0-bb1c-afe730b41fee' User entered '97.7'	System	13 Oct 2020 23:55:12
	System	13 Oct 2020 23:55:12

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:55:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c218f6f5-ddc5-40f0-bb1c-afe730b41fee' User entered 'No (N)'	System	13 Oct 2020 23:55:12
	System	13 Oct 2020 23:55:12

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:55:09', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c218f6f5-ddc5-40f0-bb1c-afe730b41fee' User entered '13 Oct 2020 18:55'	System	13 Oct 2020 23:55:12
	System	13 Oct 2020 23:55:12

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Oct 2020 15:44'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 2'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:55:28', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'dec5fd6f-853c-42e4-9fdf-fe0b554c332d' User entered 'Yes (Y)'	System	15 Oct 2020 00:55:46
	System	15 Oct 2020 00:55:46

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:55:35', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'dec5fd6f-853c-42e4-9fdf-fe0b554c332d' User entered '98.7'	System	15 Oct 2020 00:55:46
	System	15 Oct 2020 00:55:46

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:55:38', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'dec5fd6f-853c-42e4-9fdf-fe0b554c332d'	System	15 Oct 2020 00:55:46
User entered 'No (N)'	System	15 Oct 2020 00:55:46

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:55:44', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'dec5fd6f-853c-42e4-9fdf-fe0b554c332d' User entered '14 Oct 2020 19:55'	System	15 Oct 2020 00:55:46
	System	15 Oct 2020 00:55:46

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 3'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:50:50', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7628ff64-6e49-4990-9d68-e95d9ef6b826' User entered 'Yes (Y)'	System	16 Oct 2020 00:51:10
	System	16 Oct 2020 00:51:10

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:50:57', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7628ff64-6e49-4990-9d68-e95d9ef6b826' User entered '98.1'	System	16 Oct 2020 00:51:10
	System	16 Oct 2020 00:51:10

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:51:01', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7628ff64-6e49-4990-9d68-e95d9ef6b826'	System	16 Oct 2020 00:51:10
User entered 'No (N)'	System	16 Oct 2020 00:51:10

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:51:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7628ff64-6e49-4990-9d68-e95d9ef6b826' User entered '15 Oct 2020 19:51'	System	16 Oct 2020 00:51:10
	System	16 Oct 2020 00:51:10

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 4'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '052fdc67-d43a-4e3b-94f1-f69c0c61033c' User entered 'Yes (Y)'	System	16 Oct 2020 23:15:16
	System	16 Oct 2020 23:15:16

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:07', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '052fdc67-d43a-4e3b-94f1-f69c0c61033c' User entered '98.7'	System	16 Oct 2020 23:15:16
	System	16 Oct 2020 23:15:16

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:10', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '052fdc67-d43a-4e3b-94f1-f69c0c61033c'	System	16 Oct 2020 23:15:16
User entered 'No (N)'	System	16 Oct 2020 23:15:16

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:13', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '052fdc67-d43a-4e3b-94f1-f69c0c61033c' User entered '16 Oct 2020 18:15'	System	16 Oct 2020 23:15:16
	System	16 Oct 2020 23:15:16

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 5'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:33:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ce8267aa-2628-4bd3-8825-d3f879d59775' User entered 'Yes (Y)'	System	17 Oct 2020 21:33:25
	System	17 Oct 2020 21:33:25

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:33:13', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ce8267aa-2628-4bd3-8825-d3f879d59775' User entered '98.8'	System	17 Oct 2020 21:33:25
	System	17 Oct 2020 21:33:25

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:33:16', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ce8267aa-2628-4bd3-8825-d3f879d59775'	System	17 Oct 2020 21:33:25
User entered 'No (N)'	System	17 Oct 2020 21:33:25

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:33:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ce8267aa-2628-4bd3-8825-d3f879d59775' User entered '17 Oct 2020 16:33'	System	17 Oct 2020 21:33:25
	System	17 Oct 2020 21:33:25

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 6'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:13', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '443f746d-6691-473a-a52c-68e0ed80ce64' User entered 'Yes (Y)'	System	19 Oct 2020 00:13:29
	System	19 Oct 2020 00:13:29

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:19', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '443f746d-6691-473a-a52c-68e0ed80ce64' User entered '98.8'	System	19 Oct 2020 00:13:29
	System	19 Oct 2020 00:13:29

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '443f746d-6691-473a-a52c-68e0ed80ce64'	System	19 Oct 2020 00:13:29
User entered 'No (N)'	System	19 Oct 2020 00:13:29

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:27', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '443f746d-6691-473a-a52c-68e0ed80ce64' User entered '18 Oct 2020 19:13'	System	19 Oct 2020 00:13:29
	System	19 Oct 2020 00:13:29

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 7'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:13:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '9a15559f-0d96-4a48-bb1e-af8230a27e95'	System	20 Oct 2020 12:13:22
User entered 'Yes (Y)'	System	20 Oct 2020 12:13:22

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:13:09', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '9a15559f-0d96-4a48-bb1e-af8230a27e95' User entered '97.7'	System	20 Oct 2020 12:13:22
	System	20 Oct 2020 12:13:22

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:13:12', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '9a15559f-0d96-4a48-bb1e-af8230a27e95'	System	20 Oct 2020 12:13:22
User entered 'No (N)'	System	20 Oct 2020 12:13:22

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:13:21', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '9a15559f-0d96-4a48-bb1e-af8230a27e95'	System	20 Oct 2020 12:13:22
User entered '20 Oct 2020 07:13'	System	20 Oct 2020 12:13:22

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:32:40', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7667afb4-f46d-41ca-b3ca-fce627b65843'	System	13 Oct 2020 17:33:06
User entered 'None (1)'	System	13 Oct 2020 17:33:06

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:32:44', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7667afb4-f46d-41ca-b3ca-fce627b65843'	System	13 Oct 2020 17:33:06
User entered 'No (N)'	System	13 Oct 2020 17:33:06

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:32:50', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7667afb4-f46d-41ca-b3ca-fce627b65843' User entered 'No (N)'	System	13 Oct 2020 17:33:06
	System	13 Oct 2020 17:33:06

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:32:55', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7667afb4-f46d-41ca-b3ca-fce627b65843'	System	13 Oct 2020 17:33:06
User entered 'None (1)'	System	13 Oct 2020 17:33:06

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:32:59', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '7667afb4-f46d-41ca-b3ca-fce627b65843'	System	13 Oct 2020 17:33:06
User entered '13 Oct 2020 12:32'	System	13 Oct 2020 17:33:06

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Oct 2020 12:19'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Oct 2020 14:49'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:07', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'b5f18099-8484-45d9-b977-372122d8e7bf'	System	13 Oct 2020 23:51:28
User entered 'None (1)'	System	13 Oct 2020 23:51:28

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:11', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'b5f18099-8484-45d9-b977-372122d8e7bf' User entered 'No (N)'	System	13 Oct 2020 23:51:28
	System	13 Oct 2020 23:51:28

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:15', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'b5f18099-8484-45d9-b977-372122d8e7bf' User entered 'No (N)'	System	13 Oct 2020 23:51:28
	System	13 Oct 2020 23:51:28

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'b5f18099-8484-45d9-b977-372122d8e7bf'	System	13 Oct 2020 23:51:28
User entered 'None (1)'	System	13 Oct 2020 23:51:28

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:26', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'b5f18099-8484-45d9-b977-372122d8e7bf' User entered '13 Oct 2020 18:51'	System	13 Oct 2020 23:51:28
	System	13 Oct 2020 23:51:28

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Oct 2020 15:44'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 2'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:56:21', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ca2fd8a1-4d7a-478a-a0d5-d145eaa264b4'	System	15 Oct 2020 00:56:42
User entered 'None (1)'	System	15 Oct 2020 00:56:42

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:56:25', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ca2fd8a1-4d7a-478a-a0d5-d145eaa264b4'	System	15 Oct 2020 00:56:42
User entered 'No (N)'	System	15 Oct 2020 00:56:42

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:56:30', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ca2fd8a1-4d7a-478a-a0d5-d145eaa264b4'	System	15 Oct 2020 00:56:42
User entered 'No (N)'	System	15 Oct 2020 00:56:42

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:56:34', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ca2fd8a1-4d7a-478a-a0d5-d145eaa264b4'	System	15 Oct 2020 00:56:42
User entered 'None (1)'	System	15 Oct 2020 00:56:42

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:56:38', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'ca2fd8a1-4d7a-478a-a0d5-d145eaa264b4'	System	15 Oct 2020 00:56:42
User entered '14 Oct 2020 19:56'	System	15 Oct 2020 00:56:42

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 3'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:51:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0d1fe57-0e0a-4377-b579-649417900ea2'	System	16 Oct 2020 00:51:47
User entered 'None (1)'	System	16 Oct 2020 00:51:47

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:51:26', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0d1fe57-0e0a-4377-b579-649417900ea2'	System	16 Oct 2020 00:51:47
User entered 'No (N)'	System	16 Oct 2020 00:51:47

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:51:30', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0d1fe57-0e0a-4377-b579-649417900ea2'	System	16 Oct 2020 00:51:47
User entered 'No (N)'	System	16 Oct 2020 00:51:47

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:51:39', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0d1fe57-0e0a-4377-b579-649417900ea2'	System	16 Oct 2020 00:51:47
User entered 'None (1)'	System	16 Oct 2020 00:51:47

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:51:43', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c0d1fe57-0e0a-4377-b579-649417900ea2' User entered '15 Oct 2020 19:51'	System	16 Oct 2020 00:51:47
	System	16 Oct 2020 00:51:47

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 4'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:18', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4bb5bc3b-3f42-4340-b4c5-3b5cea203f67'	System	16 Oct 2020 23:15:39
User entered 'None (1)'	System	16 Oct 2020 23:15:39

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4bb5bc3b-3f42-4340-b4c5-3b5cea203f67'	System	16 Oct 2020 23:15:39
User entered 'No (N)'	System	16 Oct 2020 23:15:39

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:25', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4bb5bc3b-3f42-4340-b4c5-3b5cea203f67'	System	16 Oct 2020 23:15:39
User entered 'No (N)'	System	16 Oct 2020 23:15:39

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:27', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4bb5bc3b-3f42-4340-b4c5-3b5cea203f67'	System	16 Oct 2020 23:15:39
User entered 'None (1)'	System	16 Oct 2020 23:15:39

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:36', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4bb5bc3b-3f42-4340-b4c5-3b5cea203f67'	System	16 Oct 2020 23:15:39
User entered '16 Oct 2020 18:15'	System	16 Oct 2020 23:15:39

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 5'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:33:27', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4c315277-d9b0-4211-8446-970c10f1d430'	System	17 Oct 2020 21:33:53
User entered 'None (1)'	System	17 Oct 2020 21:33:53

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:33:30', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4c315277-d9b0-4211-8446-970c10f1d430'	System	17 Oct 2020 21:33:53
User entered 'No (N)'	System	17 Oct 2020 21:33:53

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:33:39', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4c315277-d9b0-4211-8446-970c10f1d430'	System	17 Oct 2020 21:33:53
User entered 'No (N)'	System	17 Oct 2020 21:33:53

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:33:45', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4c315277-d9b0-4211-8446-970c10f1d430'	System	17 Oct 2020 21:33:53
User entered 'None (1)'	System	17 Oct 2020 21:33:53

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:33:51', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4c315277-d9b0-4211-8446-970c10f1d430' User entered '17 Oct 2020 16:33'	System	17 Oct 2020 21:33:53
	System	17 Oct 2020 21:33:53

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 6'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:33', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '248012b8-8a53-4c46-ad0d-e717c88a5876'	System	19 Oct 2020 00:13:51
User entered 'None (1)'	System	19 Oct 2020 00:13:51

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:36', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '248012b8-8a53-4c46-ad0d-e717c88a5876' User entered 'No (N)'	System	19 Oct 2020 00:13:51
	System	19 Oct 2020 00:13:51

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:39', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '248012b8-8a53-4c46-ad0d-e717c88a5876' User entered 'No (N)'	System	19 Oct 2020 00:13:51
	System	19 Oct 2020 00:13:51

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:45', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '248012b8-8a53-4c46-ad0d-e717c88a5876'	System	19 Oct 2020 00:13:51
User entered 'None (1)'	System	19 Oct 2020 00:13:51

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:48', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '248012b8-8a53-4c46-ad0d-e717c88a5876' User entered '18 Oct 2020 19:13'	System	19 Oct 2020 00:13:51
	System	19 Oct 2020 00:13:51

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 7'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:29', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '69bc1d6b-6f77-4aa1-9f3a-14770529188a' User entered 'None (1)'	System	20 Oct 2020 12:12:48
	System	20 Oct 2020 12:12:48

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:32', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '69bc1d6b-6f77-4aa1-9f3a-14770529188a' User entered 'No (N)'	System	20 Oct 2020 12:12:48
	System	20 Oct 2020 12:12:48

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:35', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '69bc1d6b-6f77-4aa1-9f3a-14770529188a' User entered 'No (N)'	System	20 Oct 2020 12:12:48
	System	20 Oct 2020 12:12:48

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:42', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '69bc1d6b-6f77-4aa1-9f3a-14770529188a' User entered 'None (1)'	System	20 Oct 2020 12:12:48
	System	20 Oct 2020 12:12:48

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:46', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '69bc1d6b-6f77-4aa1-9f3a-14770529188a' User entered '20 Oct 2020 07:12'	System	20 Oct 2020 12:12:48
	System	20 Oct 2020 12:12:48

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:33:05', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'cc7da9d5-0443-4acc-b55c-23246500f621' User entered 'None (0)'	System	13 Oct 2020 17:33:37
	System	13 Oct 2020 17:33:37

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:33:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'cc7da9d5-0443-4acc-b55c-23246500f621' User entered 'None (0)'	System	13 Oct 2020 17:33:37
	System	13 Oct 2020 17:33:37

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:33:12', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'cc7da9d5-0443-4acc-b55c-23246500f621' User entered 'None (0)'	System	13 Oct 2020 17:33:37
	System	13 Oct 2020 17:33:37

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:33:16', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'cc7da9d5-0443-4acc-b55c-23246500f621' User entered 'None (0)'	System	13 Oct 2020 17:33:37
	System	13 Oct 2020 17:33:37

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:33:20', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'cc7da9d5-0443-4acc-b55c-23246500f621' User entered 'None (0)'	System	13 Oct 2020 17:33:37
	System	13 Oct 2020 17:33:37

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:33:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'cc7da9d5-0443-4acc-b55c-23246500f621' User entered 'None (0)'	System	13 Oct 2020 17:33:37
	System	13 Oct 2020 17:33:37

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:33:29', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'cc7da9d5-0443-4acc-b55c-23246500f621' User entered 'No (N)'	System	13 Oct 2020 17:33:37
	System	13 Oct 2020 17:33:37

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T12:33:33', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'cc7da9d5-0443-4acc-b55c-23246500f621' User entered '13 Oct 2020 12:33'	System	13 Oct 2020 17:33:37
	System	13 Oct 2020 17:33:37

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Oct 2020 12:19'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Oct 2020 14:49'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:36', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f095b624-071c-4263-9175-39667b727adb' User entered 'None (0)'	System	13 Oct 2020 23:52:43
	System	13 Oct 2020 23:52:43

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:47', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f095b624-071c-4263-9175-39667b727adb' User entered 'None (0)'	System	13 Oct 2020 23:52:43
	System	13 Oct 2020 23:52:43

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:49', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f095b624-071c-4263-9175-39667b727adb' User entered 'None (0)'	System	13 Oct 2020 23:52:43
	System	13 Oct 2020 23:52:43

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:53', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f095b624-071c-4263-9175-39667b727adb' User entered 'None (0)'	System	13 Oct 2020 23:52:43
	System	13 Oct 2020 23:52:43

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:55', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f095b624-071c-4263-9175-39667b727adb' User entered 'None (0)'	System	13 Oct 2020 23:52:43
	System	13 Oct 2020 23:52:43

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:51:58', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f095b624-071c-4263-9175-39667b727adb' User entered 'None (0)'	System	13 Oct 2020 23:52:43
	System	13 Oct 2020 23:52:43

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:52:05', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f095b624-071c-4263-9175-39667b727adb' User entered 'No (N)'	System	13 Oct 2020 23:52:43
	System	13 Oct 2020 23:52:43

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-13T18:52:40', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f095b624-071c-4263-9175-39667b727adb' User entered '13 Oct 2020 18:52'	System	13 Oct 2020 23:52:43
	System	13 Oct 2020 23:52:43

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '13 Oct 2020 15:44'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 2'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:56:44', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fead70b-62fc-4258-b805-a83203f65187' User entered 'None (0)'	System	15 Oct 2020 00:57:29
	System	15 Oct 2020 00:57:29

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:56:56', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fead70b-62fc-4258-b805-a83203f65187' User entered 'None (0)'	System	15 Oct 2020 00:57:29
	System	15 Oct 2020 00:57:29

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:56:59', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fead70b-62fc-4258-b805-a83203f65187' User entered 'None (0)'	System	15 Oct 2020 00:57:29
	System	15 Oct 2020 00:57:29

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:57:02', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fead70b-62fc-4258-b805-a83203f65187' User entered 'None (0)'	System	15 Oct 2020 00:57:29
	System	15 Oct 2020 00:57:29

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:57:05', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fead70b-62fc-4258-b805-a83203f65187' User entered 'None (0)'	System	15 Oct 2020 00:57:29
	System	15 Oct 2020 00:57:29

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:57:15', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fead70b-62fc-4258-b805-a83203f65187'	System	15 Oct 2020 00:57:29
User entered 'No interference with activity (1)'	System	15 Oct 2020 00:57:29

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:57:21', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fead70b-62fc-4258-b805-a83203f65187' User entered 'No (N)'	System	15 Oct 2020 00:57:29
	System	15 Oct 2020 00:57:29

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-14T19:57:27', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4fead70b-62fc-4258-b805-a83203f65187' User entered '14 Oct 2020 19:57'	System	15 Oct 2020 00:57:29
	System	15 Oct 2020 00:57:29

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 3'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:51:52', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4147d15c-9778-43e9-be91-5c1b4a1f5cda' User entered 'None (0)'	System	16 Oct 2020 00:52:28
	System	16 Oct 2020 00:52:28

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:51:58', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4147d15c-9778-43e9-be91-5c1b4a1f5cda'	System	16 Oct 2020 00:52:28
User entered 'No interference with activity (1)'	System	16 Oct 2020 00:52:28

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:52:02', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4147d15c-9778-43e9-be91-5c1b4a1f5cda' User entered 'None (0)'	System	16 Oct 2020 00:52:28
	System	16 Oct 2020 00:52:28

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:52:09', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4147d15c-9778-43e9-be91-5c1b4a1f5cda' User entered 'None (0)'	System	16 Oct 2020 00:52:28
	System	16 Oct 2020 00:52:28

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:52:12', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4147d15c-9778-43e9-be91-5c1b4a1f5cda' User entered 'None (0)'	System	16 Oct 2020 00:52:28
	System	16 Oct 2020 00:52:28

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:52:16', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4147d15c-9778-43e9-be91-5c1b4a1f5cda' User entered 'None (0)'	System	16 Oct 2020 00:52:28
	System	16 Oct 2020 00:52:28

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:52:20', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4147d15c-9778-43e9-be91-5c1b4a1f5cda' User entered 'No (N)'	System	16 Oct 2020 00:52:28
	System	16 Oct 2020 00:52:28

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-15T19:52:25', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '4147d15c-9778-43e9-be91-5c1b4a1f5cda' User entered '15 Oct 2020 19:52'	System	16 Oct 2020 00:52:28
	System	16 Oct 2020 00:52:28

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 4'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:46', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '41ac2f1c-a927-4a9a-a0cc-807d15528af3' User entered 'None (0)'	System	16 Oct 2020 23:16:13
	System	16 Oct 2020 23:16:13

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:49', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '41ac2f1c-a927-4a9a-a0cc-807d15528af3' User entered 'None (0)'	System	16 Oct 2020 23:16:13
	System	16 Oct 2020 23:16:13

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:57', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '41ac2f1c-a927-4a9a-a0cc-807d15528af3' User entered 'None (0)'	System	16 Oct 2020 23:16:13
	System	16 Oct 2020 23:16:13

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:15:59', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '41ac2f1c-a927-4a9a-a0cc-807d15528af3' User entered 'None (0)'	System	16 Oct 2020 23:16:13
	System	16 Oct 2020 23:16:13

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:16:02', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '41ac2f1c-a927-4a9a-a0cc-807d15528af3' User entered 'None (0)'	System	16 Oct 2020 23:16:13
	System	16 Oct 2020 23:16:13

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:16:04', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '41ac2f1c-a927-4a9a-a0cc-807d15528af3' User entered 'None (0)'	System	16 Oct 2020 23:16:13
	System	16 Oct 2020 23:16:13

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:16:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '41ac2f1c-a927-4a9a-a0cc-807d15528af3' User entered 'No (N)'	System	16 Oct 2020 23:16:13
	System	16 Oct 2020 23:16:13

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-16T18:16:11', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '41ac2f1c-a927-4a9a-a0cc-807d15528af3'	System	16 Oct 2020 23:16:13
User entered '16 Oct 2020 18:16'	System	16 Oct 2020 23:16:13

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 5'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:34:24', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '6b09ba3c-8fc6-4da8-b3d4-0c94ed97d8ab' User entered 'None (0)'	System	17 Oct 2020 21:34:54
	System	17 Oct 2020 21:34:54

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:34:27', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '6b09ba3c-8fc6-4da8-b3d4-0c94ed97d8ab' User entered 'None (0)'	System	17 Oct 2020 21:34:54
	System	17 Oct 2020 21:34:54

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:34:30', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '6b09ba3c-8fc6-4da8-b3d4-0c94ed97d8ab' User entered 'None (0)'	System	17 Oct 2020 21:34:54
	System	17 Oct 2020 21:34:54

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:34:33', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '6b09ba3c-8fc6-4da8-b3d4-0c94ed97d8ab' User entered 'None (0)'	System	17 Oct 2020 21:34:54
	System	17 Oct 2020 21:34:54

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:34:35', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '6b09ba3c-8fc6-4da8-b3d4-0c94ed97d8ab' User entered 'None (0)'	System	17 Oct 2020 21:34:54
	System	17 Oct 2020 21:34:54

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:34:37', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '6b09ba3c-8fc6-4da8-b3d4-0c94ed97d8ab' User entered 'None (0)'	System	17 Oct 2020 21:34:54
	System	17 Oct 2020 21:34:54

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:34:47', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '6b09ba3c-8fc6-4da8-b3d4-0c94ed97d8ab' User entered 'No (N)'	System	17 Oct 2020 21:34:54
	System	17 Oct 2020 21:34:54

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-17T16:34:51', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '6b09ba3c-8fc6-4da8-b3d4-0c94ed97d8ab' User entered '17 Oct 2020 16:34'	System	17 Oct 2020 21:34:54
	System	17 Oct 2020 21:34:54

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 6'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:52', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c724cf28-29a9-4889-9249-4f9b29600e7f' User entered 'None (0)'	System	19 Oct 2020 00:14:18
	System	19 Oct 2020 00:14:18

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:55', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c724cf28-29a9-4889-9249-4f9b29600e7f' User entered 'None (0)'	System	19 Oct 2020 00:14:18
	System	19 Oct 2020 00:14:18

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:13:59', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c724cf28-29a9-4889-9249-4f9b29600e7f' User entered 'None (0)'	System	19 Oct 2020 00:14:18
	System	19 Oct 2020 00:14:18

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:14:01', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c724cf28-29a9-4889-9249-4f9b29600e7f' User entered 'None (0)'	System	19 Oct 2020 00:14:18
	System	19 Oct 2020 00:14:18

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:14:04', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c724cf28-29a9-4889-9249-4f9b29600e7f' User entered 'None (0)'	System	19 Oct 2020 00:14:18
	System	19 Oct 2020 00:14:18

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:14:06', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c724cf28-29a9-4889-9249-4f9b29600e7f' User entered 'None (0)'	System	19 Oct 2020 00:14:18
	System	19 Oct 2020 00:14:18

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:14:10', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c724cf28-29a9-4889-9249-4f9b29600e7f' User entered 'No (N)'	System	19 Oct 2020 00:14:18
	System	19 Oct 2020 00:14:18

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-18T19:14:14', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'c724cf28-29a9-4889-9249-4f9b29600e7f' User entered '18 Oct 2020 19:14'	System	19 Oct 2020 00:14:18
	System	19 Oct 2020 00:14:18

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	13 Oct 2020 17:11:41
User entered 'Day 7'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:07', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f92081ba-f58b-413f-a429-f4451dd84ba2'	System	20 Oct 2020 12:12:26
User entered 'None (0)'	System	20 Oct 2020 12:12:26

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:09', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f92081ba-f58b-413f-a429-f4451dd84ba2'	System	20 Oct 2020 12:12:26
User entered 'None (0)'	System	20 Oct 2020 12:12:26

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:11', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f92081ba-f58b-413f-a429-f4451dd84ba2'	System	20 Oct 2020 12:12:26
User entered 'None (0)'	System	20 Oct 2020 12:12:26

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:14', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f92081ba-f58b-413f-a429-f4451dd84ba2'	System	20 Oct 2020 12:12:26
User entered 'None (0)'	System	20 Oct 2020 12:12:26

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:17', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f92081ba-f58b-413f-a429-f4451dd84ba2'	System	20 Oct 2020 12:12:26
User entered 'None (0)'	System	20 Oct 2020 12:12:26

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:19', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f92081ba-f58b-413f-a429-f4451dd84ba2'	System	20 Oct 2020 12:12:26
User entered 'None (0)'	System	20 Oct 2020 12:12:26

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f92081ba-f58b-413f-a429-f4451dd84ba2'	System	20 Oct 2020 12:12:26
User entered 'No (N)'	System	20 Oct 2020 12:12:26

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-10-20T07:12:25', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f92081ba-f58b-413f-a429-f4451dd84ba2'	System	20 Oct 2020 12:12:26
User entered '20 Oct 2020 07:12'	System	20 Oct 2020 12:12:26

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 17:11:41

US3922088

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 10:16:35

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 17:11:41

US3922088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:51:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:51:16

US3922088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:51:45
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 21:51:16

US3922088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:51:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 21:51:16

US3922088

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:51:45
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 21:51:16

US3922088

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:54:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 21:51:22

US3922088

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'I'	System	20 Oct 2020 21:51:22

US3922088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:54:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 19:02:21

US3922088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:54:16
User entered '29 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 19:02:21

US3922088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:54:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Oct 2020 19:02:21

US3922088

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:54:16
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 19:02:21

US3922088

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 22:54:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 19:02:26

US3922088

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'I'	System	29 Oct 2020 19:02:26

US3922088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:02:36
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	04 Nov 2020 18:01:16

US3922088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:02:36
User entered '4 Nov 2020'	Pauline Jackson (b) (4)	04 Nov 2020 18:01:16

US3922088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:02:36
User entered 'Contact Made (CONTACT MADE)'	Pauline Jackson (b) (4)	04 Nov 2020 18:01:16

US3922088

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:02:36
User entered empty.	Pauline Jackson (b) (4)	04 Nov 2020 18:01:16

US3922088

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:02:43
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	04 Nov 2020 18:01:23

US3922088

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'I'	System	04 Nov 2020 18:01:23

US3922088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:03:51
User entered 'Yes (Y)'	Pamela Echols (b) (4)	13 Nov 2020 15:15:44

US3922088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:03:51
User entered '12 Nov 2020'	Pamela Echols (b) (4)	13 Nov 2020 15:15:44

US3922088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:03:51
User entered 'Clinic (Clinic)'	Pamela Echols (b) (4)	13 Nov 2020 15:15:44

US3922088

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'VISIT3'	System	13 Nov 2020 15:15:44

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:08
User entered 'No (N)'	Pamela Echols (b) (4)	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:08
User entered empty.	Pamela Echols (b) (4)	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:08
User entered empty.	Pamela Echols (b) (4)	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered empty.	System	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:08
User entered empty.	Pamela Echols (b) (4)	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:08
User entered empty.	Pamela Echols (b) (4)	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:08
User entered empty.	Pamela Echols (b) (4)	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:08
User entered empty.	Pamela Echols (b) (4)	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered empty.	System	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:08
User entered empty.	Pamela Echols (b) (4)	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered empty.	System	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:08
User entered empty.	Pamela Echols (b) (4)	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered empty.	System	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:08
User entered empty.	Pamela Echols (b) (4)	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered empty.	System	13 Nov 2020 15:15:56

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22

US3922088

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Mar 2021 08:48:22

US3922088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:02
User entered 'No (N)'	Pamela Echols (b) (4)	13 Nov 2020 15:16:08

US3922088

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:02
User entered empty.	Pamela Echols (b) (4)	13 Nov 2020 15:16:08

US3922088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:26
User entered 'Yes (Y)'	Pamela Echols (b) (4)	13 Nov 2020 15:36:08

US3922088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:26
User entered '12 Nov 2020'	Pamela Echols (b) (4)	13 Nov 2020 15:36:08

US3922088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 01:37:23
User closed query 'Please note that source V3 states 09:24, however, lab flow chart captures 09:26. Please review EDC against source and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	15 Jan 2021 01:37:21
Query 'Please note that source V3 states 09:24, however, lab flow chart captures 09:26. Please review EDC against source and update as necessary.' answered with 'updated ' (Site from CRA).	lynn yauch (b) (4) (b) (4)	14 Jan 2021 15:08:44
User entered '09:26' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	14 Jan 2021 15:07:54
User opened query 'Please note that source V3 states 09:24, however, lab flow chart captures 09:26. Please review EDC against source and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 23:05:30
DataPoint Un-verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:50
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:26
User entered '09:24'	Pamela Echols (b) (4) (b) (4)	13 Nov 2020 15:36:08

US3922088

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '12 Nov 2020 09:26'	System	14 Jan 2021 15:07:54
User entered '12 Nov 2020 09:24'	System	13 Nov 2020 15:36:08

US3922088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:30
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 23:04:45
User entered 'Yes (Y)'	Pamela Echols (b) (4)	13 Nov 2020 15:36:17

US3922088

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered '1'	System	13 Nov 2020 15:36:17

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 64'	System	08 Sep 2020 19:09:25

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41
Data entry locked.	System	08 Sep 2020 19:09:25
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 19:09:25

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:08:41
Data entry locked.	System	08 Sep 2020 19:09:25
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered 'Day 71'	System	08 Sep 2020 19:09:25

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-11-15T14:47:12', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f0cc283c-50af-486e-b5ec-bbd1dc538f57'	System	15 Nov 2020 20:47:49
User entered 'No (N)'	System	15 Nov 2020 20:47:49

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-11-15T14:47:40', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f0cc283c-50af-486e-b5ec-bbd1dc538f57'	System	15 Nov 2020 20:47:49
User entered 'No (N)'	System	15 Nov 2020 20:47:49

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-11-15T14:47:47', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f0cc283c-50af-486e-b5ec-bbd1dc538f57' User entered '15 Nov 2020 14:47:47'	System	15 Nov 2020 20:47:49
	System	15 Nov 2020 20:47:49

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 19:09:25

US3922088

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:16:11
Data entry locked.	System	08 Sep 2020 19:09:25
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 19:09:25

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-11-20T18:04:06', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'b50acd7f-df70-4190-ab7c-7eb9df23c86d'	System	21 Nov 2020 00:04:37
User entered 'No (N)'	System	21 Nov 2020 00:04:37

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-11-20T18:04:25', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'b50acd7f-df70-4190-ab7c-7eb9df23c86d'	System	21 Nov 2020 00:04:37
User entered 'No (N)'	System	21 Nov 2020 00:04:37

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-11-20T18:04:32', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'b50acd7f-df70-4190-ab7c-7eb9df23c86d' User entered '20 Nov 2020 18:04:32'	System	21 Nov 2020 00:04:37

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-11-26T12:35:04', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '9ce529fd-29df-42aa-80b9-fdc059531ba5'	System	26 Nov 2020 18:47:37
User entered 'No (N)'	System	26 Nov 2020 18:47:37

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-11-26T12:46:31', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '9ce529fd-29df-42aa-80b9-fdc059531ba5'	System	26 Nov 2020 18:47:37
User entered 'Yes (Y)'	System	26 Nov 2020 18:47:37

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-11-26T12:47:15', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '9ce529fd-29df-42aa-80b9-fdc059531ba5'	System	26 Nov 2020 18:47:37
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Nov 2020 18:47:37

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-11-26T12:47:28', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '9ce529fd-29df-42aa-80b9-fdc059531ba5' User entered '26 Nov 2020 12:47:28'	System	26 Nov 2020 18:47:37
	System	26 Nov 2020 18:47:37

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-04T08:47:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e6a59b6b-b08b-4e16-b854-45b8aa110ace' User entered 'No (N)'	System	04 Dec 2020 14:47:23
	System	04 Dec 2020 14:47:23

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-04T08:47:15', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e6a59b6b-b08b-4e16-b854-45b8aa110ace' User entered 'No (N)'	System	04 Dec 2020 14:47:23
	System	04 Dec 2020 14:47:23

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-04T08:47:20', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e6a59b6b-b08b-4e16-b854-45b8aa110ace' User entered '04 Dec 2020 08:47:20'	System	04 Dec 2020 14:47:23
	System	04 Dec 2020 14:47:23

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-12T21:35:50', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'a8fbd8b4-b619-4001-b9e6-965876767352'	System	13 Dec 2020 03:36:04
User entered 'No (N)'	System	13 Dec 2020 03:36:04

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-12T21:35:56', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'a8fbd8b4-b619-4001-b9e6-965876767352'	System	13 Dec 2020 03:36:04
User entered 'No (N)'	System	13 Dec 2020 03:36:04

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-12T21:36:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'a8fbd8b4-b619-4001-b9e6-965876767352'	System	13 Dec 2020 03:36:04
User entered '12 Dec 2020 21:36:00'	System	13 Dec 2020 03:36:04

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-17T12:55:09', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '406dd078-8d3e-44d2-88bd-436c90c93a7d'	System	17 Dec 2020 18:55:27
User entered 'No (N)'	System	17 Dec 2020 18:55:27

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-17T12:55:18', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '406dd078-8d3e-44d2-88bd-436c90c93a7d'	System	17 Dec 2020 18:55:27
User entered 'No (N)'	System	17 Dec 2020 18:55:27

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-17T12:55:24', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '406dd078-8d3e-44d2-88bd-436c90c93a7d' User entered '17 Dec 2020 12:55:24'	System	17 Dec 2020 18:55:27
	System	17 Dec 2020 18:55:27

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-24T22:08:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2a414b4d-1e80-4a3b-bf2d-2079257ccc2b' User entered 'No (N)'	System	25 Dec 2020 04:08:29
	System	25 Dec 2020 04:08:29

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-24T22:08:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2a414b4d-1e80-4a3b-bf2d-2079257ccc2b' User entered 'No (N)'	System	25 Dec 2020 04:08:29
	System	25 Dec 2020 04:08:29

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-24T22:08:27', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '2a414b4d-1e80-4a3b-bf2d-2079257ccc2b' User entered '24 Dec 2020 22:08:27'	System	25 Dec 2020 04:08:29
	System	25 Dec 2020 04:08:29

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-31T07:39:14', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '15454d51-5f49-4d9a-bb26-d4a3b1a030b0' User entered 'No (N)'	System	31 Dec 2020 13:39:35
	System	31 Dec 2020 13:39:35

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-31T07:39:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '15454d51-5f49-4d9a-bb26-d4a3b1a030b0' User entered 'No (N)'	System	31 Dec 2020 13:39:35
	System	31 Dec 2020 13:39:35

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2020-12-31T07:39:30', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '15454d51-5f49-4d9a-bb26-d4a3b1a030b0' User entered '31 Dec 2020 07:39:30'	System	31 Dec 2020 13:39:35
	System	31 Dec 2020 13:39:35

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-09T12:18:22', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f46e81fa-3485-4476-ae4b-a103ba5039db' User entered 'No (N)'	System	09 Jan 2021 18:19:13
	System	09 Jan 2021 18:19:13

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-09T12:19:05', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f46e81fa-3485-4476-ae4b-a103ba5039db'	System	09 Jan 2021 18:19:13
User entered 'No (N)'	System	09 Jan 2021 18:19:13

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-09T12:19:11', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'f46e81fa-3485-4476-ae4b-a103ba5039db' User entered '09 Jan 2021 12:19:11'	System	09 Jan 2021 18:19:13
	System	09 Jan 2021 18:19:13

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-14T11:50:08', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e66a114a-c527-40c6-8673-576f8a990c1d'	System	14 Jan 2021 17:50:24
User entered 'No (N)'	System	14 Jan 2021 17:50:24

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-14T11:50:13', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e66a114a-c527-40c6-8673-576f8a990c1d'	System	14 Jan 2021 17:50:24
User entered 'No (N)'	System	14 Jan 2021 17:50:24

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-14T11:50:17', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'e66a114a-c527-40c6-8673-576f8a990c1d' User entered '14 Jan 2021 11:50:17'	System	14 Jan 2021 17:50:24
	System	14 Jan 2021 17:50:24

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-23T12:14:54', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0d54c1a2-7385-43bb-ba0d-1d89031ccc38'	System	23 Jan 2021 18:15:06
User entered 'No (N)'	System	23 Jan 2021 18:15:06

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-23T12:15:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0d54c1a2-7385-43bb-ba0d-1d89031ccc38'	System	23 Jan 2021 18:15:06
User entered 'No (N)'	System	23 Jan 2021 18:15:06

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-23T12:15:03', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0d54c1a2-7385-43bb-ba0d-1d89031ccc38' User entered '23 Jan 2021 12:15:03'	System	23 Jan 2021 18:15:06
	System	23 Jan 2021 18:15:06

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-28T17:03:25', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0e634216-2b5a-49a0-b49e-1c8c64cffe29'	System	28 Jan 2021 23:05:37
User entered 'No (N)'	System	28 Jan 2021 23:05:37

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-28T17:03:31', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0e634216-2b5a-49a0-b49e-1c8c64cffe29'	System	28 Jan 2021 23:05:37
User entered 'No (N)'	System	28 Jan 2021 23:05:37

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-01-28T17:03:36', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0e634216-2b5a-49a0-b49e-1c8c64cffe29' User entered '28 Jan 2021 17:03:36'	System	28 Jan 2021 23:05:37
	System	28 Jan 2021 23:05:37

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-05T12:45:28', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '789725fa-21e5-405d-a37d-acc88f9a01dd' User entered 'No (N)'	System	05 Feb 2021 18:45:43

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-05T12:45:34', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '789725fa-21e5-405d-a37d-acc88f9a01dd' User entered 'No (N)'	System	05 Feb 2021 18:45:43

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-05T12:45:40', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '789725fa-21e5-405d-a37d-acc88f9a01dd' User entered '05 Feb 2021 12:45:40'	System	05 Feb 2021 18:45:43
	System	05 Feb 2021 18:45:43

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-18T11:13:19', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '8671a5a2-20fe-4492-a2d0-cca784d2ba67'	System	18 Feb 2021 17:17:40
User entered 'No (N)'	System	18 Feb 2021 17:17:40

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-18T11:13:23', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '8671a5a2-20fe-4492-a2d0-cca784d2ba67'	System	18 Feb 2021 17:17:40
User entered 'No (N)'	System	18 Feb 2021 17:17:40

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-18T11:13:31', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '8671a5a2-20fe-4492-a2d0-cca784d2ba67'	System	18 Feb 2021 17:17:40
User entered '18 Feb 2021 11:13:31'	System	18 Feb 2021 17:17:40

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-26T08:18:39-06:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '49463df4-03c1-4424-afe2-f675221862b0'	System	26 Feb 2021 14:19:00
User entered 'No (N)'	System	26 Feb 2021 14:19:00

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-26T08:18:44-06:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '49463df4-03c1-4424-afe2-f675221862b0'	System	26 Feb 2021 14:19:00
User entered 'No (N)'	System	26 Feb 2021 14:19:00

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-26T08:18:56-06:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '49463df4-03c1-4424-afe2-f675221862b0'	System	26 Feb 2021 14:19:00
User entered '26 Feb 2021 14:18:56'	System	26 Feb 2021 14:19:00

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-03-07T21:07:26-06:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5b60ac00-a033-4395-af2f-d37b3fb9278f' User entered 'No (N)'	System	08 Mar 2021 03:12:17
	System	08 Mar 2021 03:12:17

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-03-07T21:07:34-06:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5b60ac00-a033-4395-af2f-d37b3fb9278f' User entered 'No (N)'	System	08 Mar 2021 03:12:17
	System	08 Mar 2021 03:12:17

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-03-07T21:07:41-06:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '5b60ac00-a033-4395-af2f-d37b3fb9278f' User entered '07 Mar 2021 21:07:41'	System	08 Mar 2021 03:12:17
	System	08 Mar 2021 03:12:17

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-18T22:38:47-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '973f7184-5088-461b-bd16-4430cf50f8f2'	System	24 Mar 2021 02:08:46
User entered 'Yes (Y)'	System	24 Mar 2021 02:08:46

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-18T22:39:01-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '973f7184-5088-461b-bd16-4430cf50f8f2'	System	24 Mar 2021 02:08:46
User entered 'No (N)'	System	24 Mar 2021 02:08:46

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-18T22:39:09-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '973f7184-5088-461b-bd16-4430cf50f8f2'	System	24 Mar 2021 02:08:46
User entered 'No (N)'	System	24 Mar 2021 02:08:46

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-18T22:39:18-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '973f7184-5088-461b-bd16-4430cf50f8f2'	System	24 Mar 2021 02:08:46
User entered 'Yes (Y)'	System	24 Mar 2021 02:08:46

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Please 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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-18T22:39:47-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '973f7184-5088-461b-bd16-4430cf50f8f2'	System	24 Mar 2021 02:08:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Mar 2021 02:08:46

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-18T22:39:52-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '973f7184-5088-461b-bd16-4430cf50f8f2'	System	24 Mar 2021 02:08:46
User entered '18 Mar 2021 22:39:52'	System	24 Mar 2021 02:08:46

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-25T06:44:48-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0278ceec-4e69-4495-bb9a-191001b133dc' User entered 'Yes (Y)'	System	25 Mar 2021 11:45:49
	System	25 Mar 2021 11:45:49

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-25T06:44:54-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0278ceec-4e69-4495-bb9a-191001b133dc'	System	25 Mar 2021 11:45:49
User entered 'No (N)'	System	25 Mar 2021 11:45:49

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-25T06:45:03-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0278ceec-4e69-4495-bb9a-191001b133dc'	System	25 Mar 2021 11:45:49
User entered 'No (N)'	System	25 Mar 2021 11:45:49

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-25T06:45:12-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0278ceec-4e69-4495-bb9a-191001b133dc' User entered 'Yes (Y)'	System	25 Mar 2021 11:45:49
	System	25 Mar 2021 11:45:49

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-25T06:45:26-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0278ceec-4e69-4495-bb9a-191001b133dc'	System	25 Mar 2021 11:45:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Mar 2021 11:45:49

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-03-25T06:45:36-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '0278ceec-4e69-4495-bb9a-191001b133dc' User entered '25 Mar 2021 06:45:36'	System	25 Mar 2021 11:45:49
	System	25 Mar 2021 11:45:49

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-02T13:30:44-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'dd67ee38-0c55-4c08-b974-31ddf1e58acb' User entered 'Yes (Y)'	System	02 Apr 2021 18:31:22
	System	02 Apr 2021 18:31:22

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-02T13:30:48-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'dd67ee38-0c55-4c08-b974-31ddf1e58acb' User entered 'No (N)'	System	02 Apr 2021 18:31:22
	System	02 Apr 2021 18:31:22

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-02T13:30:52-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'dd67ee38-0c55-4c08-b974-31ddf1e58acb' User entered 'No (N)'	System	02 Apr 2021 18:31:22
	System	02 Apr 2021 18:31:22

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-02T13:30:58-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'dd67ee38-0c55-4c08-b974-31ddf1e58acb' User entered 'Yes (Y)'	System	02 Apr 2021 18:31:22
	System	02 Apr 2021 18:31:22

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Please 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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-02T13:31:03-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'dd67ee38-0c55-4c08-b974-31ddf1e58acb'	System	02 Apr 2021 18:31:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Apr 2021 18:31:22

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-02T13:31:08-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: 'dd67ee38-0c55-4c08-b974-31ddf1e58acb' User entered '02 Apr 2021 13:31:08'	System	02 Apr 2021 18:31:22
	System	02 Apr 2021 18:31:22

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-08T21:26:37-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '33eb732d-c986-4c26-9bbf-70634496b462'	System	09 Apr 2021 02:26:52
User entered 'No (N)'	System	09 Apr 2021 02:26:52

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-08T21:26:42-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '33eb732d-c986-4c26-9bbf-70634496b462'	System	09 Apr 2021 02:26:52
User entered 'No (N)'	System	09 Apr 2021 02:26:52

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-08T21:26:48-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '33eb732d-c986-4c26-9bbf-70634496b462'	System	09 Apr 2021 02:26:52
User entered '08 Apr 2021 21:26:48'	System	09 Apr 2021 02:26:52

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-15T09:29:45-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '82186e60-ca20-409b-a71f-852980856471' User entered 'No (N)'	System	15 Apr 2021 14:29:57
	System	15 Apr 2021 14:29:57

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-15T09:29:48-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '82186e60-ca20-409b-a71f-852980856471'	System	15 Apr 2021 14:29:57
User entered 'No (N)'	System	15 Apr 2021 14:29:57

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-15T09:29:53-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '82186e60-ca20-409b-a71f-852980856471' User entered '15 Apr 2021 09:29:53'	System	15 Apr 2021 14:29:57
	System	15 Apr 2021 14:29:57

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-23T10:07:09-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '02b67f24-7ffa-4a9e-af66-acb3429a9ea0'	System	23 Apr 2021 15:07:20
User entered 'No (N)'	System	23 Apr 2021 15:07:20

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

Have you been exposed to someone with 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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-23T10:07:12-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '02b67f24-7ffa-4a9e-af66-acb3429a9ea0'	System	23 Apr 2021 15:07:20
User entered 'No (N)'	System	23 Apr 2021 15:07:20

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-04-23T10:07:18-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '02b67f24-7ffa-4a9e-af66-acb3429a9ea0'	System	23 Apr 2021 15:07:20
User entered '23 Apr 2021 10:07:18'	System	23 Apr 2021 15:07:20

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-05-01T13:11:01-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '246cfe85-6dfd-4b1f-9597-8b0bc0391508'	System	01 May 2021 18:11:11
User entered 'No (N)'	System	01 May 2021 18:11:11

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Have you been exposed to someone with 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 (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-05-01T13:11:04-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '246cfe85-6dfd-4b1f-9597-8b0bc0391508'	System	01 May 2021 18:11:11
User entered 'No (N)'	System	01 May 2021 18:11:11

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C7F42A7C-FF32-4650-9472-34519FE7749E)', Time: '2021-05-01T13:11:07-05:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '246cfe85-6dfd-4b1f-9597-8b0bc0391508'	System	01 May 2021 18:11:11
User entered '01 May 2021 13:11:07'	System	01 May 2021 18:11:11

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:08:41

US3922088

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:16:35

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:08:41
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:08:41

US3922088

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:16:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-28T16:52:45-06:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '04963f31-0638-4591-a4f0-33752eff1dcb' User entered 'No (N)'	System	28 Feb 2021 22:52:55
	System	28 Feb 2021 22:52:55

US3922088

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:16:35

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 07:18:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4B6C3FBE-9406-4AB4-936B-12ECE326833F)', Time: '2021-02-28T16:52:54-06:00', User OID: 'PatientReportedOutcome (US3922088)', ODM File OID: '04963f31-0638-4591-a4f0-33752eff1dcb' User entered '28 Feb 2021 22:52:54'	System	28 Feb 2021 22:52:55
	System	28 Feb 2021 22:52:55

US3922088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:23:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	08 Dec 2020 22:16:43

US3922088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:23:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered '08 Dec 2020'	Pauline Jackson (b) (4)	08 Dec 2020 22:16:43

US3922088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:23:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Pauline Jackson (b) (4) (b) (4)	08 Dec 2020 22:16:43

US3922088

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:23:23
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered empty.	Pauline Jackson (b) (4)	08 Dec 2020 22:16:43

US3922088

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:23:34
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered 'Yes (Y)'	Pauline Jackson (b) (4)	08 Dec 2020 22:17:10

US3922088

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Mar 2021 08:48:22
User entered 'I'	System	08 Dec 2020 22:17:10

US3922088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:21
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered 'Yes (Y)'	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	08 Jan 2021 17:40:33

US3922088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:21
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered '8 Jan 2021'	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	08 Jan 2021 17:40:33

US3922088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:21
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	08 Jan 2021 17:40:33

US3922088

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:21
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered empty.	Jennifer Ruiz (b) (4)	08 Jan 2021 17:40:33

US3922088

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:28
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered 'Yes (Y)'	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	08 Jan 2021 17:40:38

US3922088

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
User entered 'I'	System	08 Jan 2021 17:40:38

US3922088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:39
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered 'Yes (Y)'	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	10 Feb 2021 17:41:39

US3922088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:39
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered '10 Feb 2021'	Jennifer Ruiz (b) (4)	10 Feb 2021 17:41:39

US3922088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:39
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	10 Feb 2021 17:41:39

US3922088

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:39
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered empty.	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	10 Feb 2021 17:41:39

US3922088

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 15:24:47
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User entered 'Yes (Y)'	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	10 Feb 2021 17:41:43

US3922088

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:17:10
User entered 'I'	System	10 Feb 2021 17:41:43

US3922088

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:03:56
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:37:17
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	11 Mar 2021 22:30:38

US3922088

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:03:56
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:37:17
User entered '11 Mar 2021'	Jennifer Ruiz (b) (4)	11 Mar 2021 22:30:38

US3922088

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:03:56
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:37:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jennifer Ruiz (b) (4) (b) (4)	11 Mar 2021 22:30:38

US3922088

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:16:35

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:03:56
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:37:17
User entered empty.	Jennifer Ruiz (b) (4)	11 Mar 2021 22:30:38

US3922088

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:04:00
User signature succeeded.	Michele Reynolds (b) (4)	11 Mar 2021 22:37:17
User entered 'Yes (Y)'	Jennifer Ruiz (b) (4)	11 Mar 2021 22:30:43

US3922088

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:05
User entered 'I'	System	11 Mar 2021 22:30:43

US3922088

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Apr 2021 21:00:31
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered '12 Apr 2021'	lynn yauch (b) (4)	14 Apr 2021 21:00:31
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered 'Clinic (Clinic)'	lynn yauch (b) (4)	14 Apr 2021 21:00:31
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	14 Apr 2021 21:00:31

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered 'No (N)'	lynn yauch (b) (4)	14 Apr 2021 21:04:23
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 21:04:23
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 21:04:23
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 21:04:23

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 21:04:23
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 21:04:23
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 21:04:23
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 21:04:23
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 21:04:23

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 21:04:23
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 21:04:23

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 21:04:23
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 21:04:23

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered empty.	lynn yauch (b) (4)	14 Apr 2021 21:04:23
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:16:35

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Apr 2021 21:04:23

US3922088

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Apr 2021 21:03:57
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:16:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered '12 Apr 2021'	lynn yauch (b) (4)	14 Apr 2021 21:03:57
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 13:22:43
	(b) (4)	
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Apr 2021 21:00:37
	(b) (4)	

US3922088

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:16:35

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 21:00:37

US3922088

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:10:58
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered 'Yes (Y)'	Lorine Cook (b) (4)	02 Mar 2021 21:14:51
	(b) (4)	

US3922088

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:10:58
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered '02 Mar 2021'	Lorine Cook (b) (4)	02 Mar 2021 21:14:51
	(b) (4)	

US3922088

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

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 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:10:58
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered 'Clinic (Clinic)'	Lorine Cook (b) (4)	02 Mar 2021 21:14:51
	(b) (4)	

US3922088

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

Form: Visit Date

Generated On: 10 Jun 2021 10:16:35

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User entered 'UNBLND_DECIDE'	System	02 Mar 2021 21:14:51

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:11:11
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered '02 Mar 2021'	Lorine Cook (b) (4)	02 Mar 2021 21:15:39
	(b) (4)	

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:28:41
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 15:58:27
	(b) (4)	
User entered '0'	lynn yauch (b) (4)	22 Apr 2021 14:00:48
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:50:11

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:11:11
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered 'Yes (Y)'	Lorine Cook (b) (4)	02 Mar 2021 21:15:39
	(b) (4)	

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 13:10:14
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 20:28:39
User signature succeeded.	Michele Reynolds (b) (4)	22 Apr 2021 15:58:27
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated per query' (Site from DM).	lynn yauch (b) (4)	22 Apr 2021 14:01:11
User entered 'Amendment 6 or later (Amendment 6 or later)'	lynn yauch (b) (4)	22 Apr 2021 14:00:48
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:07:44
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:50:11

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:11:11
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered '02 Mar 2021'	Lorine Cook (b) (4)	02 Mar 2021 21:15:39
	(b) (4)	

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:11:11
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Lorine Cook (b) (4)	02 Mar 2021 21:15:39
	(b) (4)	

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:11:11
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Lorine Cook (b) (4)	02 Mar 2021 21:15:39
	(b) (4)	

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:11:11
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
User entered 'mRNA-1273 (mRNA-1273)'	Lorine Cook (b) (4)	02 Mar 2021 21:15:39

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:11:11
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered 'No (N)'	Lorine Cook (b) (4)	02 Mar 2021 21:15:39
	(b) (4)	

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User entered empty.	System	02 Mar 2021 21:15:39

US3922088

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

Form: Unblinding

Generated On: 10 Jun 2021 10:16:35

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User entered empty.	System	02 Mar 2021 21:15:39

US3922088

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:11:21
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered 'Yes (Y)'	Lorine Cook (b) (4)	02 Mar 2021 21:16:06
	(b) (4)	

US3922088

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:11:21
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered '02 Mar 2021'	Lorine Cook (b) (4)	02 Mar 2021 21:16:06
	(b) (4)	

US3922088

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:11:21
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered '14:42'	Lorine Cook (b) (4)	02 Mar 2021 21:16:06
	(b) (4)	

US3922088

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User entered '02 Mar 2021 14:42'	System	02 Mar 2021 21:16:06

US3922088

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:12:04
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered 'Yes (Y)'	Lorine Cook (b) (4)	02 Mar 2021 21:16:23
	(b) (4)	

US3922088

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:12:04
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered '02 Mar 2021'	Lorine Cook (b) (4)	02 Mar 2021 21:16:23
	(b) (4)	

US3922088

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 19:12:04
User signature succeeded.	Michele Reynolds (b) (4)	03 Mar 2021 16:20:02
	(b) (4)	
User entered '14:45'	Lorine Cook (b) (4)	02 Mar 2021 21:16:23
	(b) (4)	

US3922088

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:22
User entered '02 Mar 2021 14:45'	System	02 Mar 2021 21:16:23

US3922088

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:16:35

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:29:11
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 14:50:32
User entered 'Yes (Y)' reason for change: Data Entry Error	lynn yauch (b) (4)	25 Sep 2020 15:34:28
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:45:06

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 07:28:03

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:16:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in elbow - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:43:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 13:43:55
Data point term sent to Coder	System	25 Sep 2020 15:36:25
User entered 'sparadic dull pain right elbow'	lynn yauch (b) (4) (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered 'No (N)'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered 'No (N)'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered '18 Sep 2020'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered empty.	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User entered empty.	System	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered 'No (N)' reason for change: Data Entry Error	lynn yauch (b) (4)	21 Oct 2020 19:19:56
User entered 'Yes (Y)'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered '14 Oct 2020' reason for change: Data Entry Error	lynn yauch (b) (4)	21 Oct 2020 19:19:56
User entered empty.	(b) (4) lynn yauch (b) (4) (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered empty.	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User entered empty.	System	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered 'Grade 1/Mild (Grade 1/Mild)'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered 'No (N)'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered '0'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered '0'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered '0'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered empty.	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered empty.	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered empty.	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered empty.	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered '0'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered '0'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered '0'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered 'Not Related (NOT RELATED)'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:16:38
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 15:35:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 15:35:47
User entered 'None (NONE)' reason for change:	lynn yauch (b) (4)	25 Sep 2020 15:35:47
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 15:35:31
User entered empty.	lynn yauch (b) (4) (b) (4)	25 Sep 2020 15:35:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:16:38
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Sep 2020 15:35:47
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4)	25 Sep 2020 15:35:47
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	25 Sep 2020 15:35:31
User entered '0'	lynn yauch (b) (4) (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered '0'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered '0'	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	21 Oct 2020 19:19:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	lynn yauch (b) (4) (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered empty.	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:16:38
User entered empty.	lynn yauch (b) (4)	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User entered '0'	System	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:28:03
User entered '0'	System	25 Sep 2020 15:35:31

US3922088

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 07:28:03

US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:27:08
User entered 'USA-US212-2021-mRNA-1273-P301000007'	System	15 Mar 2021 16:43:25
User entered 'New'	(b) (4), (b) (6)	15 Mar 2021 16:43:25

US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: please provide the outcome of the event ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 05:48:49
Query 'Per MM: please provide the outcome of the event ' answered with 'updated per query' (Site from DM). DataPoint Verified.	lynn yauch (b) (4) (b) (4)	14 Apr 2021 21:05:04
User opened query 'Per MM: please provide the outcome of the event ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User opened query 'PV query: Please consider to update event term to final diagnosis once available' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 09:54:14
User coded data point as SOC: Endocrine disorders, HLGT: Adrenal gland disorders, HLT: Adrenal gland disorders NEC, PT: Adrenal mass, LLT: Adrenal mass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 17:55:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Mar 2021 17:55:01
Data point term sent to Coder	System	12 Mar 2021 17:54:29
User entered 'Adrenal Mass'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered 'Yes (Y)'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered 'No (N)'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered 'No (N)'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered '10 Mar 2021'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered empty.	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 17:53:57

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:05:22
DataPoint Un-verified.	lynn yauch (b) (4)	14 Apr 2021 21:05:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	14 Apr 2021 21:05:46
DataPoint Verified.	lynn yauch (b) (4)	14 Apr 2021 21:05:46
DataPoint Verified.	(b) (4)	08 Apr 2021 15:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 15:50:13
	Lorine Cook (b) (4)	12 Mar 2021 17:53:57
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:05:20
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 14:23:42
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated per query' (Site from Safety).	lynn yauch (b) (4)	14 Apr 2021 21:06:04
DataPoint Un-verified.	lynn yauch (b) (4)	14 Apr 2021 21:05:46
User entered '24 Mar 2021' reason for change: Data Entry Error	lynn yauch (b) (4)	14 Apr 2021 21:05:46
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:02:36
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered empty.	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	07 Apr 2021 17:55:25
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	07 Apr 2021 17:53:48
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Mar 2021 17:54:57
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Mar 2021 17:53:57
User entered 'Yes (Y)'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 06:21:42
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'site to update pending medical records' (Site from System).	lynn yauch (b) (4) (b) (4)	14 Apr 2021 21:08:03
User closed query 'PER CDM: RE-QUERY: Per response 'per source, subject was NOT admitted to ICU, therefore there is additional data to record,. However, Admitted to ICU? was left blank. Pleaser review and record the data as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:28:16
Query 'Please read the question, as it currently notes that hospitalization was already occurring for subject, and the SAE is causing prolonged hospitalized. Please review and clarify if this should be selected or not. ' canceled (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 15:50:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Apr 2021 17:55:25
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	07 Apr 2021 17:55:25
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	07 Apr 2021 17:55:25
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	07 Apr 2021 17:55:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	07 Apr 2021 17:53:48
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	07 Apr 2021 17:53:48
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	07 Apr 2021 17:53:48
User entered '0' reason for change: Data Entry Error	lynn yauch (b) (4)	07 Apr 2021 17:53:48
Query 'PER CDM: RE-QUERY: Per response 'per source, subject was NOT admitted to ICU, therefore there is additional data to record,. However, Admitted to ICU? was left blank. Pleaser review and record the data as appropriate. Thank you.' answered with 'ICU line updated per query' (Site from DM).	lynn yauch (b) (4)	07 Apr 2021 17:52:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	07 Apr 2021 17:51:59
User opened query 'Please read the question, as it currently notes that hospitalization was already occurring for subject, and the SAE is causing prolonged hospitalized. Please review and clarify if this should be selected or not. ' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 14:27:54
User opened query 'PER CDM: RE-QUERY: Per response 'per source, subject was NOT admitted to ICU, therefore there is additional data to record,. However, Admitted to ICU? was left blank. Pleaser review and record the data as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 11:32:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PER CDM: RE-QUERY: Response noted. However, please record data for Admitted to ICU? and other related fields. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 11:32:39
Query 'PER CDM: RE-QUERY: Response noted. However, please record data for Admitted to ICU? and other related fields. Thank you.' answered with 'per source, subject was NOT admitted to ICU, therefore there is additional data to record' (Site from DM).	lynn yauch (b) (4)	15 Mar 2021 14:13:28
User opened query 'PER CDM: RE-QUERY: Response noted. However, please record data for Admitted to ICU? and other related fields. Thank you.' (Site from DM).	(b) (4)	15 Mar 2021 06:24:17
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Mar 2021 06:23:34
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Hospital date of admission is recorded.' (Site from System).	Lorine Cook (b) (4)	12 Mar 2021 17:55:40
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	12 Mar 2021 17:54:57
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	12 Mar 2021 17:54:57
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Mar 2021 17:54:57
User entered '1' reason for change: Data Entry Error	Lorine Cook (b) (4)	12 Mar 2021 17:54:57

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Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). User entered '0'	System	12 Mar 2021 17:53:57
	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered '11 Mar 2021'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Please clarify if end date is known, per source, subject was contacted on 02Apr2021 to send medical records since site has yet to receive to date.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:08:24
Query 'Please clarify if end date is known, per source,lynn yauch subject was contacted on 02Apr2021 to send medical records since site has yet to receive to date.' answered with 'updated per query' (Site from CRA).	(b) (4)	14 Apr 2021 21:06:26
User opened query 'Please clarify if end date is known, per source, subject was contacted on 02Apr2021 to send medical records since site has yet to receive to date.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 15:51:39
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:04:03
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered 'No (N)' reason for change: Data Entry Error	lynn yauch (b) (4)	07 Apr 2021 17:51:59
User entered empty.	Lorine Cook (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered empty.	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:13
User entered '0'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:06
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:04
User entered 'Not Related (NOT RELATED)'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:47:59
User entered 'Not Applicable (NOT APPLICABLE)'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:14
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Mar 2021 14:14:37
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Mar 2021 17:53:57
User entered '0'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide 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)	22 Apr 2021 21:33:57
User opened query 'PER CDM: Re-Query: As per previous response it was reported as 'Pending Medical Records.'. However, request you please keep this query open until site get records and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:41:25
User closed query 'Per CDM: Concomitant Medication is recorded "Yes". However there is no corresponding CM Medication record in Prior / concomitant Medication and Vaccination with same start date and end date. Please review and update accordingly or else clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 11:41:25
Query 'Per CDM: Concomitant Medication is recorded "Yes". However there is no corresponding CM Medication record in Prior / concomitant Medication and Vaccination with same start date and end date. Please review and update accordingly or else clarify. ' answered with 'Pending Medical Records' (Site from DM).	lynn yauch (b) (4) (b) (4)	19 Apr 2021 19:14:56
User closed query 'PV Query: Please provide 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)	15 Apr 2021 14:23:45

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide 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.' answered with 'pending medical records' (Site from Safety). DataPoint Verified.	lynn yauch (b) (4) (b) (4)	14 Apr 2021 21:06:57
	(b) (4), (b) (6)	08 Apr 2021 15:48:17
User opened query 'PV Query: Please provide 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)	22 Mar 2021 13:03:01
User opened query 'Per CDM: Concomitant Medication is recorded "Yes". However there is no corresponding CM Medication record in Prior / concomitant Medication and Vaccination with same start date and end date. Please review and update accordingly or else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:11:37
User entered '1' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	15 Mar 2021 14:14:37
User entered '0'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
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)	22 Apr 2021 21:33:37
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 21:33:03
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:19
User entered '0'	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:08:41
User closed query 'Source currently blank under outcome, please review EDC and source and reconcile.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 15:08:38
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)	15 Apr 2021 14:23:47
Query 'Source currently blank under outcome, please review EDC and source and reconcile.' answered with 'updated per query' (Site from CRA).	lynn yauch (b) (4)	14 Apr 2021 21:07:15
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 'updated per query' (Site from Safety).	lynn yauch (b) (4)	14 Apr 2021 21:07:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	lynn yauch (b) (4)	14 Apr 2021 21:05:46
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 15:50:21
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:45
User opened query 'Source currently blank under outcome, please review EDC and source and reconcile.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 15:48:44
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)	22 Mar 2021 13:02:49
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Mar 2021 14:14:01

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[Outcome](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Mar 2021 14:14:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	lynn yauch (b) (4) (b) (4)	15 Mar 2021 14:14:01
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Mar 2021 17:53:57
User entered empty.	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:47
User entered empty.	Lorine Cook (b) (4) (b) (4)	12 Mar 2021 17:53:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 15:10:46
User closed 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)	20 Apr 2021 15:10:42
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.' answered with 'no results are available, Medical Records have been requested' (Site from Safety).	lynn yauch (b) (4) (b) (4)	19 Apr 2021 19:14:27
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending medical records' (Site from Safety).	lynn yauch (b) (4) (b) (4)	19 Apr 2021 19:13:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:48:52
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 Mar 2021 13:04:13
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)	22 Mar 2021 13:03:53

PRODUCTION RELEASE (v12.003
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US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject is still currently in hospital getting all test done possible surgery. Will send for Medical records.'	Lorine Cook (b) (4)	12 Mar 2021 17:53:57

US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 17:53:57

US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Mar 2021 17:53:57

US3922088

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:16:35

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Apr 2021 17:51:59

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:29:11
User closed query 'Source indicates subject received Morphine (11Mar2021), unknown strength, duration, and ongoing. Source notes Dilaudid received (11Mar2021), unknown strength, duration, etc. Both medications were taken for treatment of SAE 'Adrenal Mass.' Please enter into EDC as soon as possible, even if unknown fields. Please contact patient and hospital to receive information on doses, etc.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 21:48:42
Query 'Source indicates subject received Morphine (11Mar2021), unknown strength, duration, and ongoing. Source notes Dilaudid received (11Mar2021), unknown strength, duration, etc. Both medications were taken for treatment of SAE 'Adrenal Mass.' Please enter into EDC as soon as possible, even if unknown fields. Please contact patient and hospital to receive information on doses, etc.' answered with 'site to updated once medical records are received' (Site from CRA).	lynn yauch (b) (4) (b) (4)	14 Apr 2021 21:09:14
User opened query 'Source indicates subject received Morphine (11Mar2021), unknown strength, duration, and ongoing. Source notes Dilaudid received (11Mar2021), unknown strength, duration, etc. Both medications were taken for treatment of SAE 'Adrenal Mass.' Please enter into EDC as soon as possible, even if unknown fields. Please contact patient and hospital to receive information on doses, etc.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 15:54:53
User signature succeeded.	Michele Reynolds (b) (4) (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:17:49
User entered 'Yes (Y)'	lynn yauch (b) (4) (b) (4)	11 Sep 2020 13:45:14

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 13:47:41
User coded data point as Term Coded data point by	Coder Import (b) (4)	11 Sep 2020 13:47:41
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	11 Sep 2020 13:46:25
User entered 'pravastatin'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'hypercholesterolemia'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '20'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'mg (mg)'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'once daily (QD)'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'un UNK 2015'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:46:08
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:46:08

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:46:08

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 13:46:08

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 13:47:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 13:47:42
Data point term sent to Coder	System	11 Sep 2020 13:47:25
User entered 'levothyroxine'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'hypothyroidism'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '88'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:27:32
User closed query 'please note that this medication dosing is usually in micrograms for this high of a dosage. if going to list in milligrams, need to update the decimal / strength in source / edc. please review and update in edc and source as necessary.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 23:27:25
Query 'please note that this medication dosing is usually in micrograms for this high of a dosage. if going to list in milligrams, need to update the decimal / strength in source / edc. please review and update in edc and source as necessary.' answered with 'mcg' (Site from CRA).	Lorine Cook (b) (4)	10 Nov 2020 21:05:31
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Lorine Cook (b) (4)	10 Nov 2020 21:05:19
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:24:12
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User opened query 'please note that this medication dosing is usually in micrograms for this high of a dosage. if going to list in milligrams, need to update the decimal / strength in source / edc. please review and update in edc and source as necessary.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:19:28
User entered 'mg (mg)'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:27:29
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	10 Nov 2020 21:05:38
DataPoint Un-verified.	Lorine Cook (b) (4)	10 Nov 2020 21:05:38
	(b) (4)	
User entered 'mcg' reason for change: Data Entry Error	Lorine Cook (b) (4)	10 Nov 2020 21:05:38
	(b) (4)	
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	10 Nov 2020 21:05:19
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'once daily (QD)'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'un UNK 2017'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:46:43
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:46:43

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:46:43

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 13:46:43

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Nov 2020 20:49:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:49:52
Data point term sent to Coder Coding entries removed.	System Lorine Cook (b) (4) (b) (4)	10 Nov 2020 21:13:22 10 Nov 2020 21:13:03
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	06 Nov 2020 16:22:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 08:38:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Sep 2020 08:38:54
Data point term sent to Coder User entered 'meloxicam'	System lynn yauch (b) (4) (b) (4)	11 Sep 2020 13:48:28 11 Sep 2020 13:47:40

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:29:30
DataPoint Un-verified.	Lorine Cook (b) (4)	10 Nov 2020 21:13:03
	(b) (4)	
User entered 'R hand TRIGGER FINGER' reason	Lorine Cook (b) (4)	10 Nov 2020 21:13:03
for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'trigger finger'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '15'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'mg (mg)'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'other (OTHER)'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 23:29:04
User closed query 'please write out this frequency, appears to be 3 times per week.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 23:29:02
Query 'please write out this frequency, appears to be 3 times per week.' answered with 'corrected' (Site from CRA).	Lorine Cook (b) (4)	10 Nov 2020 21:06:56
	(b) (4)	
User entered '3 times per week' reason for change:	Lorine Cook (b) (4)	10 Nov 2020 21:06:47
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:24:08
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User opened query 'please write out this frequency, appears to be 3 times per week.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:20:22
User entered 'Q3W'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'un UNK 2017'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:47:40
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 13:47:40

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 13:47:40

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 13:47:40

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 13:49:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 13:49:38
Data point term sent to Coder	System	11 Sep 2020 13:48:30
User entered 'mulitvitamin'	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User closed query 'Per DM CLR: This medication was given as a SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:47:36
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:29:42
Query 'Per DM CLR: This medication was given as a SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.	Lorine Cook (b) (4)	10 Nov 2020 21:07:32
' answered with 'corrected ' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Lorine Cook (b) (4)	10 Nov 2020 21:07:25
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	
User opened query 'Per DM CLR: This medication was given as a SUPPLEMENT. Review response to 'Prophylaxis' if should be updated to 'YES'. Update as applicable.	Lorine Cook (b) (4)	10 Nov 2020 21:07:25
' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 09:10:45
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 16:22:31
	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'supplement'	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'I'	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'tablet (TABLET)'	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'once daily (QD)'	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'un UNK 2015'	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:48:28
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:48:28

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:48:28

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 13:48:28

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 13:50:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 13:50:41
Data point term sent to Coder	System	11 Sep 2020 13:49:32
User entered 'aspirin'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'cardiac prophylaxis'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '81'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'mg (mg)'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'once daily (QD)'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Oral (ORAL)'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'un UNK 2015'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:49:05
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:49:05

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 13:49:05

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 13:49:05

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:22:31
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) (b) (4)	11 Sep 2020 14:27:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 14:27:34
Data point term sent to Coder	System	11 Sep 2020 13:50:36
User entered 'flu vaccine'	lynn yauch (b) (4) (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User closed query 'please ensure source indicates 'yes' for prophylaxis as well. Currently missing in source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:30:03
Query 'please ensure source indicates 'yes' for prophylaxis as well. Currently missing in source.' answered with 'corrected' (Site from CRA).	Lorine Cook (b) (4)	10 Nov 2020 21:09:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:23:17
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:23:13
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User opened query 'please ensure source indicates 'yes' for prophylaxis as well. Currently missing in source.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:21:22
User entered 'Yes (Y)'	lynn yauch (b) (4)	11 Sep 2020 13:50:12
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'flu prophylaxis'	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User closed query 'please note typical dose per administration is 0.5 mL; please review and update in EDC / source as necessary. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:21:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:31:00
Query 'please note typical dose per administration is 0.5 mL; please review and update in EDC / source as necessary. Thank you.' answered with 'updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	10 Nov 2020 21:09:15
User entered '0.5' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	10 Nov 2020 21:09:00
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:23:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User opened query 'please note typical dose per administration is 0.5 mL; please review and update in EDC / source as necessary. Thank you.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered '1'	lynn yauch (b) (4) (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User closed query 'please note typical dose per administration is 0.5 mL; please review and update in EDC / source as necessary. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 21:21:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:31:02
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	10 Nov 2020 21:10:21
Query 'please note typical dose per administration is 0.5 mL; please review and update in EDC / source as necessary. Thank you.' answered with 'updated ' (Site from CRA).	Lorine Cook (b) (4) (b) (4)	10 Nov 2020 21:09:22
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	10 Nov 2020 21:09:00
User entered 'mL (mL)' reason for change: Data Entry Error	Lorine Cook (b) (4) (b) (4)	10 Nov 2020 21:09:00
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:23:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User opened query 'please note typical dose per administration is 0.5 mL; please review and update in EDC / source as necessary. Thank you.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:22:06
User entered 'Other (OTHER)'	lynn yauch (b) (4) (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:31:04
User entered empty; reason for change Data Entry Error	Lorine Cook (b) (4)	10 Nov 2020 21:10:21
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 16:23:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'dose'	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'once (ONCE)'	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Intramuscular (INTRAMUSCULAR)'	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '22 Aug 2020'	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '0'	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '22 Aug 2020'	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User entered empty.	System	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User entered empty.	System	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:53:22
User entered empty.	System	11 Sep 2020 13:50:12

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 16:39:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 16:39:34
Data point term sent to Coder	System	14 Oct 2020 16:38:43
User entered 'flonase'	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
User closed query 'Per DM CLR: this Con Med was added on 06 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 10:21:15
Query 'Per DM CLR: this Con Med was added on 06 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Subject stated seasonal allergies did not worsen, he just decided to get a prescription, but "rarely uses it."' (Site from DM).	Pauline Jackson (b) (4) (b) (4)	08 Dec 2020 22:15:24
User opened query 'Per DM CLR: this Con Med was added on 06 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 03:02:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'seasonal allergies'	lynn yauch (b) (4) (b) (4)	14 Oct 2020 16:38:25

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'I'	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'puff (PUFF)'	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'once daily (QD)'	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Nasal (NASAL)'	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '06 Oct 2020'	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered '0'	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'Yes (Y)'	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

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

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered empty.	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:22:31
User entered 'No (N)'	lynn yauch (b) (4)	14 Oct 2020 16:38:25
	(b) (4)	

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:38:25

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 16:38:25

US3922088

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:16:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 16:38:25

US3922088

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:16:35

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User closed query 'Source indicates during SAE hospitalization for adrenal mass, that patient received CT scan. Please review and clarify and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:54:57
Query 'Source indicates during SAE hospitalization for adrenal mass, that patient received CT scan. Please review and clarify and update as applicable.' answered with 'Data to be updated upon receipt of Medical Records' (Site from CRA).	lynn yauch (b) (4) (b) (4)	19 Apr 2021 19:16:12
User opened query 'Source indicates during SAE hospitalization for adrenal mass, that patient received CT scan. Please review and clarify and update as applicable.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 15:58:01
User signature succeeded.	Michele Reynolds (b) (4)	22 Feb 2021 20:42:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 23:09:28
User entered 'No (N)'	lynn yauch (b) (4) (b) (4)	11 Nov 2020 15:40:03

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:33
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:29
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'USA-US212-2021-MRNA-1273-P301000007'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:24
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:57
User entered 'Yes (Y)'	System	07 Apr 2021 17:55:25
Un-reviewed for Safety.	System	07 Apr 2021 17:53:48
Signature has been broken.	System	07 Apr 2021 17:53:48
User entered 'No (N)'	System	07 Apr 2021 17:53:48
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Yes (Y)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:24
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:57
User entered 'Yes (Y)'	System	07 Apr 2021 17:55:25
Un-reviewed for Safety.	System	07 Apr 2021 17:53:48
Signature has been broken.	System	07 Apr 2021 17:53:48
User entered 'No (N)'	System	07 Apr 2021 17:53:48
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Yes (Y)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Jennifer'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Bashour'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'US'	System	15 Mar 2021 16:43:43

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Apr 2021 14:24:07
User entered '2'	System	08 Apr 2021 15:29:55
User entered '1'	System	15 Mar 2021 16:43:43

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:33
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:29
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'USA-US212-2021-MRNA-1273-P301000007'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:24
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:57
User entered 'Yes (Y)'	System	07 Apr 2021 17:55:25
Un-reviewed for Safety.	System	07 Apr 2021 17:53:48
Signature has been broken.	System	07 Apr 2021 17:53:48
User entered 'No (N)'	System	07 Apr 2021 17:53:48
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Yes (Y)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:24
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:57
User entered 'Yes (Y)'	System	07 Apr 2021 17:55:25
Un-reviewed for Safety.	System	07 Apr 2021 17:53:48
Signature has been broken.	System	07 Apr 2021 17:53:48
User entered 'No (N)'	System	07 Apr 2021 17:53:48
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Yes (Y)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Jennifer'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Bashour'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'US'	System	15 Mar 2021 16:43:43

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Apr 2021 14:24:07
User entered '2'	System	08 Apr 2021 15:29:55
User entered '1'	System	15 Mar 2021 16:43:43

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
User entered '15/Mar/2021 11:43'	(b) (4) System	15 Mar 2021 16:43:43

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:16:35

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)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 16:43:43

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:33
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:29
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'USA-US212-2021-MRNA-1273-P301000007'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:24
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:57
User entered 'Yes (Y)'	System	07 Apr 2021 17:55:25
Un-reviewed for Safety.	System	07 Apr 2021 17:53:48
Signature has been broken.	System	07 Apr 2021 17:53:48
User entered 'No (N)'	System	07 Apr 2021 17:53:48
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Yes (Y)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:24
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:57
User entered 'Yes (Y)'	System	07 Apr 2021 17:55:25
Un-reviewed for Safety.	System	07 Apr 2021 17:53:48
Signature has been broken.	System	07 Apr 2021 17:53:48
User entered 'No (N)'	System	07 Apr 2021 17:53:48
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Yes (Y)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Jennifer'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Bashour'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'US'	System	15 Mar 2021 16:43:43

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Apr 2021 14:24:07
User entered '2'	System	08 Apr 2021 15:29:55
User entered '1'	System	15 Mar 2021 16:43:43

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:51:58
User entered '08/Apr/2021 11:29'	System	08 Apr 2021 15:29:55

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:16:35

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)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 14:24:00
User signature succeeded.	Michele Reynolds (b) (4)	08 Apr 2021 19:16:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 15:29:55

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:33
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:29
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'USA-US212-2021-MRNA-1273-P301000007'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:24
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:57
User entered 'Yes (Y)'	System	07 Apr 2021 17:55:25
Un-reviewed for Safety.	System	07 Apr 2021 17:53:48
Signature has been broken.	System	07 Apr 2021 17:53:48
User entered 'No (N)'	System	07 Apr 2021 17:53:48
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Yes (Y)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 15:29:24
User signature succeeded.	Michele Reynolds (b) (4)	07 Apr 2021 20:59:57
User entered 'Yes (Y)'	System	07 Apr 2021 17:55:25
Un-reviewed for Safety.	System	07 Apr 2021 17:53:48
Signature has been broken.	System	07 Apr 2021 17:53:48
User entered 'No (N)'	System	07 Apr 2021 17:53:48
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Yes (Y)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'No (N)'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Jennifer'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'Bashour'	System	15 Mar 2021 16:43:25

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 15:51:58
User signature succeeded.	Michele Reynolds (b) (4)	16 Mar 2021 17:51:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:43:57
User entered 'US'	System	15 Mar 2021 16:43:43

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 10:16:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	15 Apr 2021 14:24:07
User entered '2'	System	08 Apr 2021 15:29:55
User entered '1'	System	15 Mar 2021 16:43:43

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:16:35

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:09:01
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 19:22:43
User entered '15/Apr/2021 09:24'	(b) (4) System	15 Apr 2021 14:24:07

US3922088

Folder: SAE USA-US212-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:16:35

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)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:09:01
User signature succeeded.	Michele Reynolds (b) (4)	15 Apr 2021 19:22:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:24:07