

US3742229 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

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US3742229

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 17:42:18

Generated On: 10 Jun 2021 09:30:51

Participant ID

US3742229

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

US3742229

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	71
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

US3742229

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Date of Informed Consent (<i>dd MMM yyyy</i>)	3 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) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Condition	HISTORY OF ULCERATIVE COLITIS
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

US3742229

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Condition	DEPRESSION
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)	_____

US3742229

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:01 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 10:01
Height (<i>xxx.x</i>)	61.5 in
Weight (<i>xxx.x</i>)	130.0 lb
BMI (<i>xxx.x</i>)	24.21603 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) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 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) 15 Feb 2021 17:34:43

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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

OUTDOOR SERVICES PROVIDER

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) 15 Feb 2021 17:34:43

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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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

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

What was the participant's randomization number? 189644

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) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

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) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 10:01
Temperature (xxx.x)	097.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	071 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	091 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	11:56 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 11:56
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	080 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

US3742229

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

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) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 11:18 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 11:18

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) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 SEP 2020
Collection time (00:00-23:59)	10:33 (24 HR)
Collection date and time (derived)	3 SEP 2020 10:33

US3742229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:33	3 SEP 2020 10:33
Nasopharyngeal Swab 2	No		

US3742229

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

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 09:30:51

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:04

PC Open Date & Time

03 SEP 2020 11:38

PC Close Date & Time

03 SEP 2020 14:08

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

97.6 °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	03 SEP 2020 18:45
PC Open Date & Time	03 SEP 2020 15:03
PC Close Date & Time	04 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

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

98.0 °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

05 SEP 2020 03:25

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

05 SEP 2020 17:36

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

06 SEP 2020 16:13

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

07 SEP 2020 14:33

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

97.8 °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

08 SEP 2020 12:07

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

97.4 °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 09:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 12:05

PC Open Date & Time

03 SEP 2020 11:38

PC Close Date & Time

03 SEP 2020 14:08

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

03 SEP 2020 18:46

PC Open Date & Time

03 SEP 2020 15:03

PC Close Date & Time

04 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 03:21

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

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

05 SEP 2020 17:37

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

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

06 SEP 2020 16:12

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

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

07 SEP 2020 14:34

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

08 SEP 2020 12:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

10 SEP 2020 08:58

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 12:05
PC Open Date & Time	03 SEP 2020 11:38
PC Close Date & Time	03 SEP 2020 14:08

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 18:47
PC Open Date & Time	03 SEP 2020 15:03
PC Close Date & Time	04 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 03:22
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

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 ☒

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 17:37
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 16:12
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 14:34
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

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 ☒

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 12:04
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

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 ☒

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 08:58
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3742229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742229

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3742229

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:42:34

Generated On: 10 Jun 2021 09:30:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742229

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:34

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

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)	30 SEP 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:25
Temperature (xxx.x)	098.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	075 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	080 mmHg
Diastolic Blood Pressure units	MMHG

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

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)	30 SEP 2020
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 12:36
Temperature (xxx.x)	098.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	082 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	077 mmHg
Diastolic Blood Pressure units	MMHG

US3742229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

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) 30 SEP 2020

What was the treatment time? (00:00-23:59) 12:06 (24 HR)

Treatment Date and Time (derived) 30 SEP 2020 12:06

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

US3742229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	11:18 (24 HR)
Collection date and time (derived)	30 SEP 2020 11:18

US3742229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:17	30 SEP 2020 11:17
Nasopharyngeal Swab 2	No		

US3742229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

30 SEP 2020 12:39

PC Open Date & Time

30 SEP 2020 12:26

PC Close Date & Time

30 SEP 2020 14:56

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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 98.2 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 01 OCT 2020 09:33

PC Open Date & Time 30 SEP 2020 15:51

PC Close Date & Time 01 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	01 OCT 2020 17:39
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

02 OCT 2020 19:02

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

03 OCT 2020 20:48

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

04 OCT 2020 15:18

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

06 OCT 2020 00:03

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	06 OCT 2020 21:55
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 12:10

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 12:40

PC Open Date & Time

30 SEP 2020 12:26

PC Close Date & Time

30 SEP 2020 14:56

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

01 OCT 2020 09:34

PC Open Date & Time

30 SEP 2020 15:51

PC Close Date & Time

01 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 17:42

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 19:03

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 20:49

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 15:19

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

06 OCT 2020 00:03

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 21:48

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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

No ☒

Yes ☐

PC Time stamp	30 SEP 2020 12:41
PC Open Date & Time	30 SEP 2020 12:26
PC Close Date & Time	30 SEP 2020 14:56

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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 ☒

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 09:36
PC Open Date & Time	30 SEP 2020 15:51
PC Close Date & Time	01 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 17:38
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

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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US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 19:03
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

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 ☒

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 20:49
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 15:19
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

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 ☒

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 00:04
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

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 ☒

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EAB) (1725)

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 21:48
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 07 OCT 2020 12:11

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 09 OCT 2020 01:09

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 OCT 2020 12:11
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 OCT 2020 01:09
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3742229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742229

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742229

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742229

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

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) _____

US3742229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 OCT 2020

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

US3742229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 OCT 2020
Collection time (00:00-23:59)	11:05 (24 HR)
Collection date and time (derived)	28 OCT 2020 11:05

US3742229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:34:43

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 04:52:22
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

12 NOV 2020 09:26:01

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 01:31:54
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 12:52:06
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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	28 NOV 2020 00:49:11
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 02:18:49
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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	12 DEC 2020 03:26:07
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

20 DEC 2020 17:56:40

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

26 DEC 2020 01:11:40

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 11:07:37
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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	09 JAN 2021 16:54:13
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 18:48:10

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

23 JAN 2021 10:52:45

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

01 FEB 2021 09:00:18

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 FEB 2021 08:06:05

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

13 FEB 2021 10:47:40

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

21 FEB 2021 09:04:01

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

03 MAR 2021 19:42:06

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 17:57:45

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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	15 MAR 2021 15:39:00
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 20:56:52

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 15:07:30

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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="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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	17 APR 2021 09:12:47
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 APR 2021 09:47:41
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 12:41:04
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2021 00:01
Patient Cloud Close Date & Time	30 JUN 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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°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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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°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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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="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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

DAY 754

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 <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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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°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 ☐

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3742229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:30:51

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		03 MAR 2021 19:42:38

US3742229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:42:34

Generated On: 10 Jun 2021 09:30:51

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3742229

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:34

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:42:34

Generated On: 10 Jun 2021 09:30:51

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742229

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:34

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:42:34

Generated On: 10 Jun 2021 09:30:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3742229

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:42:34

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3742229

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	VISIT4

US3742229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

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.

US3742229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	09:53 (24 HR)
Collection date and time (derived)	30 MAR 2021 09:53

US3742229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742229

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:30:51

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"/>

US3742229

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:30:51

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3742229

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:42:34

Generated On: 10 Jun 2021 09:30:51

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

Visit date (dd MMM yyyy)	27 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3742229

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:43:08

Generated On: 10 Jun 2021 09:30:51

Date of updated informed consent (*dd MMM yyyy*) 27 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 27 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3742229

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:42:34

Generated On: 10 Jun 2021 09:30:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00-23:59)	10:12 (24 HR)
Collection date and time (derived)	27 JAN 2021 10:12

US3742229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 17:42:33

Generated On: 10 Jun 2021 09:30:51

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	10:16
Collection Date and Time (derived)	27 JAN 2021 10:16

US3742229

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 21:31:58

Generated On: 10 Jun 2021 09:30:51

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

AEID

Adverse event

DIAPHORESIS

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)

30 SEP 2020

Start time (00:00-23:59)

16:00 (24 HR)

AE start date and time (derived)

30 SEP 2020 16:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

1 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

PRODUCTION RELEASE (v12.003

329 of 2205

EAB) (1725)

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" 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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

AEID

Adverse event

BROKEN TOOTH

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)

06 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 DEC 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

PRODUCTION RELEASE (v12.003

331 of 2205

EAB) (1725)

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

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

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

AEID

Adverse event

POST EXTRACTION DENTAL
INFECTION

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)

14 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 DEC 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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

AEID	
Adverse event	WORSENING DEPRESSION
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)	1 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

AEID	
Adverse event	WORSENING ANXIETY
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)	1 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

AEID	
Adverse event	CONSTIPATION
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)	3 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 26 Apr 2021 14:46:56

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

AEID	USA-US127-2021-MRNA-1273-P30 1000015
Adverse event	SEVERE MAJOR DEPRESSION WITH PSYCHOTIC FEATURES
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)	04 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" 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)	04 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 14:46:56

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 14:46:56

Generated On: 10 Jun 2021 09:30:51

PARTICIPANT US3742229 WAS HOSPITALIZED FOR ACUTE DEPRESSION FROM 04APR2021 THROUGH 09APR2021. STAFF HAD TRIED MULTIPLE TIMES TO CONTACT PARTICIPANT DUE TO A MISSED DIARY WITHOUT SUCCESS. SITE BECAME AWARE OF THE PARTICIPANT'S HOSPITALIZATION ON 12APR2021 WHEN PARTICIPANT'S WIFE LEFT A MESSAGE ON SITE'S VOICE MAIL. SITE CONTACTED PARTICIPANT AT HOME AND PARTICIPANT VERIFIED HOSPITALIZATION AND DATES.

UPDATE 1 MEDICAL RECORDS RECEIVED AND REVIEWED. PARTICIPANT WAS HOSPITALIZED FOR SEVERE MAJOR DEPRESSION WITH PSYCHOTIC FEATURES. THE PARTICIPANT, WHO WAS HOSPITALIZED UNDER EMERGENCY PETITION WAS "HALLUCINATING, DELUSIONAL AND (b) (6) (b) (6)." DURING THE INTAKE PARTICIPANT REPORTED TO THE ED PHYSICIAN THAT HE FEELS

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 26 Apr 2021 14:46:56

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LIKE HE IS BEING WATCHED
BY THE POLICE. PARTICIPANT
HAS HAD A COMPLETE
NEUROLOGICAL WORK UP AND
WITH NO EVIDENCE OF ANY
DEFICITS. PARTICIPANT WAS
STABILIZED AND SENT HOME
UNTIL ECT TREATMENTS
COULD BEGIN. PER THE
PARTICIPANT'S WIFE HE
UNDERWENT OVER (b) (6) ECT
TREATMENTS IN 2018. ECT
TREATMENTS WERE NOT
REPORTED BY THE
PARTICIPANT DURING REVIEW
OF MEDICAL HISTORY AT
STUDY ENTRANCE.
PARTICIPANT WAS HOME
BRIEFLY AND WAS
SUBSEQUENTLY READMITTED
DUE CONTINUED DEPRESSION
ALONG WITH PSYCHOSIS.
THERE WAS NO SIGNIFICANT
CHANGE, PARTICIPANT'S WIFE
WAS UNABLE TO MANAGE HIM
AT HOME. HE IS CURRENTLY
HOSPITALIZED AND REFUSING
ECT TREATMENTS.
SITE WILL CONTINUE TO
FOLLOW AND WILL SEEK
ADDITIONAL MEDICAL
RECORDS UPON
PARTICIPANT'S DISCHARGE
FROM THE HOSPITAL.

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

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 17:42:33

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication LIPITOR

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROTECTION

Dose per administration 10

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) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID REFULX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication PENTASA

Prophylaxis Yes ☐
No ☒

Indication ULCERTIVE COLITIS
PROPHYLAXIS

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication SEDATION FOR COLONOSCOPY

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	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 checked="" 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)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication NIDAZOLAN

Prophylaxis Yes ☐
No ☒

Indication SEDATION FOR COLONOSCOPY

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	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)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 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"/>

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN FEVER

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	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)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		1 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN AND
FEVER

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	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)		16 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 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"/>

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH
PROPHYLAXIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	Intraocular	<input type="radio"/>
	Intramuscular	<input 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)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication BROKEN TOOTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY FOUR HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	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)		11 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication IBUPROPEN

Prophylaxis Yes ☐
No ☒

Indication BROKEN TOOTH

Dose per administration 600

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

EVERY 6 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	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)	11 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication POST EXTRACTION DENTAL
INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication QUETIAPINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 50

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 (13)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	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)	8 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication MIRTAZAPINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING DEPRESSION

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

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	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)	24 FEB 2021	
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"/>

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

Name of Medication ATIVAN

Prophylaxis Yes ☐
No ☒

Indication WORSENING ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 07 Apr 2021 21:28:57

Generated On: 10 Jun 2021 09:30:51

	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)	3 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3742229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 17:42:33

Generated On: 10 Jun 2021 09:30:51

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 17:42:33

Generated On: 10 Jun 2021 09:30:51

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 SEP 2020	COLONSCOPY	Diagnostic	
11 DEC 2020	ORAL SURGERY	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:30:51

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3742229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:30:51

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 ☐

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 10:11:06

Generated On: 10 Jun 2021 09:30:51

SAEID	USA-US127-2021-MRNA-1273-P301000015
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 10:11:06

Generated On: 10 Jun 2021 09:30:51

SAEID	USA-US127-2021-MRNA-1273-P301000015
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	13/APR/2021 14:54
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

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 10:11:06

Generated On: 10 Jun 2021 09:30:51

SAEID	USA-US127-2021-MRNA-1273-P301000015
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	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	26/APR/2021 12:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3742229 (Prod: University of Maryland School of Medicine)

US3742229

Form: Participant Creation

Generated On: 10 Jun 2021 09:30:51

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'US3742229'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 13:45:41

US3742229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:20:50

US3742229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 13:45:42

US3742229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Clinic (Clinic)'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:20:50

US3742229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'SCRN'	System	03 Sep 2020 15:20:50

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 13:45:43

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '71'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'YEARS'	System	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered '71'	System	03 Sep 2020 15:21:08

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Male (M)'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'I'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4) (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:30:51

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:24:44

US3742229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:51

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 12:55:12
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 19:02:25
User entered '3 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	03 Sep 2020 15:21:08

US3742229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'Sep 2020'	System	03 Sep 2020 15:21:08

US3742229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered '2020'	System	03 Sep 2020 15:21:08

US3742229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:51

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Amendment 3 (3)'	(b) (4) Sherry McCammon (b) (4) (b) (4)	03 Sep 2020 15:21:08

US3742229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:21:08

US3742229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:51

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:21:08

US3742229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:51

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:21:08

US3742229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:51

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:21:08

US3742229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:51

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 13:45:42

US3742229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:30:51

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'I'	System	03 Sep 2020 15:21:15

US3742229

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:21:15

US3742229

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:30:51

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:42:54

US3742229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 16:45:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:45:45
Data point term sent to Coder	System	03 Sep 2020 16:44:34
User entered 'acid reflux'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:43:38

US3742229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'UN UNK 2010'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:43:38

US3742229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:43:38

US3742229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:43:38

US3742229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	05 Mar 2021 20:57:04
Signature has been broken.	(b) (4)	
	Sherry McCammon (b) (4)	01 Mar 2021 14:33:23
User signature succeeded.	(b) (4)	
	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4)	
	Hassan Haji (b) (4)	03 Sep 2020 16:43:38
	(b) (4)	

US3742229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:43:38

US3742229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'Jan 2010'	System	03 Sep 2020 16:43:38

US3742229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered '2010'	System	03 Sep 2020 16:43:38

US3742229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered empty.	System	03 Sep 2020 16:43:38

US3742229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered empty.	System	03 Sep 2020 16:43:38

US3742229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis ulcerative, LLT: Ulcerative colitis - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Sep 2020 23:07:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 23:07:46
Data point term sent to Coder	System	03 Sep 2020 16:44:35
User entered 'history of ulcerative colitis'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:44:23

US3742229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'UN UNK 1970'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:44:23

US3742229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:44:23

US3742229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:44:23

US3742229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:44:23

US3742229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:44:23

US3742229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'Jan 1970'	System	03 Sep 2020 16:44:23

US3742229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered '1970'	System	03 Sep 2020 16:44:23

US3742229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered empty.	System	03 Sep 2020 16:44:23

US3742229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered empty.	System	03 Sep 2020 16:44:23

US3742229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:46:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 16:46:52
Data point term sent to Coder	System	03 Sep 2020 16:45:36
User entered 'depression'	Hassan Haji (b) (4)	03 Sep 2020 16:45:05
	(b) (4)	

US3742229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'UN UNK 2017'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:45:05

US3742229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:45:05

US3742229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:27:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:27:51
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:45:05

US3742229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:27:51
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:27:51
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'UN Mar 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:45:05

US3742229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:45:05

US3742229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'Jan 2017'	System	03 Sep 2020 16:45:05

US3742229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered '2017'	System	03 Sep 2020 16:45:05

US3742229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered empty.	System	05 Apr 2021 20:27:51
User entered 'Mar 2020'	System	03 Sep 2020 16:45:05

US3742229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered empty.	System	05 Apr 2021 20:27:51
User entered '2020'	System	03 Sep 2020 16:45:05

US3742229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:51

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	05 Mar 2021 20:57:04
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Mar 2021 14:35:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:35:56
Data point term sent to Coder	System	01 Mar 2021 14:34:55
User entered 'anxiety'	Sherry McCammon (b) (4)	01 Mar 2021 14:34:20
	(b) (4)	

US3742229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	05 Mar 2021 20:57:04
User entered 'UN UNK 2015'	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 14:34:20

US3742229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	05 Mar 2021 20:57:04
User entered '0'	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 14:34:20

US3742229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:51

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	05 Mar 2021 20:57:04
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 14:34:20

US3742229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	05 Mar 2021 20:57:04
User entered empty.	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 14:34:20

US3742229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:51

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	05 Mar 2021 20:57:04
User entered '0'	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 14:34:20

US3742229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:51

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'Jan 2015'	System	01 Mar 2021 14:34:20

US3742229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered '2015'	System	01 Mar 2021 14:34:20

US3742229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered empty.	System	01 Mar 2021 14:34:20

US3742229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered empty.	System	01 Mar 2021 14:34:20

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:25:00
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 19:02:33
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '10:01'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered '3 Sep 2020 10:01'	System	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '61.5' in	(b) (4)	
	Hassan Haji (b) (4)	03 Sep 2020 16:49:05
DataPoint set to visible.	(b) (4)	
	System	03 Sep 2020 15:21:15

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '130.0' lb	(b) (4) Hassan Haji (b) (4)	03 Sep 2020 16:49:05
DataPoint set to visible.	(b) (4) System	03 Sep 2020 15:21:15

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered '24.21603'	System	03 Sep 2020 16:49:05
DataPoint set to visible.	System	03 Sep 2020 15:21:15

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'kg/m2'	System	03 Sep 2020 16:49:05
DataPoint set to visible.	System	03 Sep 2020 15:21:15

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 12:57:43
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'DATA HAS BEEN REMOVED AND ND HAS BEEN ADDED TO PREVENT DATA DUPLICATION' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 15:09:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 15:08:45
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 13:30:54
User entered '097.8' F	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:08:45
User entered 'Oral (Oral)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:08:45
User entered '071'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'bpm'	System	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:08:45
User entered '14'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'breaths/min'	System	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:08:45
User entered '155'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'mmHg'	System	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:08:45
User entered '091'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User entered 'mmHg'	System	03 Sep 2020 16:49:05

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06

US3742229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06

US3742229

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:13

US3742229

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:25:07
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 19:02:38
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:49:13

US3742229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:24:12
User entered 'No (N)' reason for change: New Information	System	03 Sep 2020 15:24:12
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	03 Sep 2020 15:24:12
User entered empty.	(b) (4)	
	System	03 Sep 2020 15:22:28
	Sherry McCammon (b) (4)	03 Sep 2020 15:22:28
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:24:12
User entered 'No (N)' reason for change: New Information	System	03 Sep 2020 15:24:12
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	03 Sep 2020 15:24:12
User entered empty.	(b) (4)	
	System	03 Sep 2020 15:22:28
	Sherry McCammon (b) (4)	03 Sep 2020 15:22:28
	(b) (4)	

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:24:12
User entered 'No (N)' reason for change: New Information	System	03 Sep 2020 15:24:12
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	03 Sep 2020 15:24:12
User entered empty.	(b) (4)	
	System	03 Sep 2020 15:22:28
	Sherry McCammon (b) (4)	03 Sep 2020 15:22:28
	(b) (4)	

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:24:12
User entered 'No (N)' reason for change: New Information	Sherry McCammon (b) (4)	03 Sep 2020 15:24:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	03 Sep 2020 15:22:28
	Sherry McCammon (b) (4)	03 Sep 2020 15:22:28
	(b) (4)	

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:24:12
User entered 'No (N)' reason for change: New Information	System	03 Sep 2020 15:24:12
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	03 Sep 2020 15:24:12
User entered empty.	(b) (4)	
	System	03 Sep 2020 15:22:28
	Sherry McCammon (b) (4)	03 Sep 2020 15:22:28
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:24:12
User entered 'No (N)' reason for change: New Information	System	03 Sep 2020 15:24:12
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	03 Sep 2020 15:24:12
User entered empty.	(b) (4)	
	System	03 Sep 2020 15:22:28
	Sherry McCammon (b) (4)	03 Sep 2020 15:22:28
	(b) (4)	

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:24:12
User entered 'No (N)' reason for change: New Information	System	03 Sep 2020 15:24:12
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	03 Sep 2020 15:24:12
User entered empty.	(b) (4)	
	System	03 Sep 2020 15:22:28
	Sherry McCammon (b) (4)	03 Sep 2020 15:22:28
	(b) (4)	

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:24:12
User entered 'No (N)' reason for change: New Information	Sherry McCammon (b) (4)	03 Sep 2020 15:24:12
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	03 Sep 2020 15:22:28
	Sherry McCammon (b) (4)	03 Sep 2020 15:22:28
	(b) (4)	

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Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:24:12
User entered 'No (N)' reason for change: New Information	System	03 Sep 2020 15:24:12
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	03 Sep 2020 15:24:12
User entered empty.	(b) (4)	
	System	03 Sep 2020 15:22:28
	Sherry McCammon (b) (4)	03 Sep 2020 15:22:28
	(b) (4)	

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 15:24:12
User entered 'No (N)' reason for change: New Information	System	03 Sep 2020 15:24:12
User opened query 'Data is required. Please complete.' (Site from System).	Sherry McCammon (b) (4)	03 Sep 2020 15:24:12
User entered empty.	(b) (4)	
	System	03 Sep 2020 15:22:28
	Sherry McCammon (b) (4)	03 Sep 2020 15:22:28
	(b) (4)	

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:22:28

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:22:28

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Outdoor services provider'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:22:28

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:22:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:22:28

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:22:28

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'I'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:22:28

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Folder: Screening

Form: Risk of Exposure

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:22:28

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:22:28

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '0'	(b) (4) Sherry McCammon (b) (4) (b) (4)	03 Sep 2020 15:22:28

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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)	30 Apr 2021 14:49:06
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) Sherry McCammon (b) (4)	03 Sep 2020 15:22:28

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Sep 2020 15:20:33

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
Query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:25:54
User opened query ' Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 19:02:43
User entered '3 Sep 2020'	Sherry McCammon (b) (4) (b) (4)	03 Sep 2020 15:20:33

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	03 Sep 2020 15:20:33

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'VISIT1'	System	03 Sep 2020 15:20:33

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '03 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 14:49:37

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '189644'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 14:49:37

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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 14:49:37

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:51

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)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	Hassan Haji (b) (4)	03 Sep 2020 16:50:08

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Folder: Visit 1 Day 1

Form: Randomization

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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)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	Hassan Haji (b) (4)	03 Sep 2020 16:50:08

US3742229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	Hassan Haji (b) (4)	03 Sep 2020 16:50:08

US3742229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:51

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	Hassan Haji (b) (4)	03 Sep 2020 16:50:08

US3742229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:51

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	Hassan Haji (b) (4)	03 Sep 2020 16:50:08

US3742229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:01:18
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:07:36
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:07:35

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:40:04
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:29:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:29:36
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:22:20
User entered '61.5' in	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:29:36
User entered '130.0' lb	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:40:04
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:29:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:29:36
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:22:20
User entered '61.5' in	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:53:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:51

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:29:36
User entered '130.0' lb	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:53:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:29:36
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '10:01'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '03 Sep 2020 10:01'	System	22 Sep 2020 13:29:36
User entered '3 Sep 2020 10:01'	System	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '097.8' F	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '071'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'bpm'	System	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '14'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'breaths/min'	System	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '155'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'mmHg'	System	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '091'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'mmHg'	System	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:51

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 14:40:04
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:29:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 13:29:36
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 12:22:20
User entered '61.5' in	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:30:51

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:29:36
User entered '130.0' lb	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:29:36
User entered '3 Sep 2020'	Hassan Haji (b) (4) (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '11:56'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '03 Sep 2020 11:56'	System	22 Sep 2020 13:29:36
User entered '3 Sep 2020 11:56'	System	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '98.2' F	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '080'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'bpm'	System	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '18'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'breaths/min'	System	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '146'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'mmHg'	System	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '076'	Hassan Haji (b) (4)	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'mmHg'	System	03 Sep 2020 16:53:23

US3742229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	17 Sep 2020 19:24:58
User entered 'Yes (Y)'	(b) (4)	
	Hassan Haji (b) (4)	03 Sep 2020 16:53:34
	(b) (4)	

US3742229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty; reason for change Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	17 Sep 2020 19:24:58
User entered '3 Sep 2020'	(b) (4)	
	Hassan Haji (b) (4)	03 Sep 2020 16:53:34
	(b) (4)	

US3742229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:29:43

US3742229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:29:43

US3742229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

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)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:29:43

US3742229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 15:29:43

US3742229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:29:43

US3742229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '11:18'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:29:43

US3742229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '3 Sep 2020 11:18'	System	03 Sep 2020 15:29:43

US3742229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 15:29:43

US3742229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'ONCE'	System	03 Sep 2020 15:29:43

US3742229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 15:29:43

US3742229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Sep 2020 15:26:19

US3742229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '3 Sep 2020'	Sherry McCammon (b) (4)	03 Sep 2020 15:26:19

US3742229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '10:33'	Sherry McCammon (b) (4)	03 Sep 2020 15:26:19

US3742229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '3 Sep 2020 10:33'	System	03 Sep 2020 15:26:19

US3742229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:30:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '3 Sep 2020'	Sherry McCammon (b) (4)	03 Sep 2020 15:26:49

US3742229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry McCammon (b) (4)	03 Sep 2020 15:26:49

US3742229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	03 Sep 2020 15:26:49

US3742229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '10:33'	Sherry McCammon (b) (4)	03 Sep 2020 15:26:49

US3742229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '3 Sep 2020 10:33'	System	03 Sep 2020 15:26:49

US3742229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry McCammon (b) (4)	03 Sep 2020 15:26:49

US3742229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	Sherry McCammon (b) (4)	03 Sep 2020 15:26:49

US3742229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Sherry McCammon (b) (4)	03 Sep 2020 15:26:49

US3742229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered empty.	System	03 Sep 2020 15:26:49

US3742229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Hassan Haji (b) (4)	03 Sep 2020 16:54:03

US3742229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '1'	System	03 Sep 2020 16:54:03

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:04:22', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2138d067-30c4-444f-a952-007639a06d60' User entered 'Yes (Y)'	System	03 Sep 2020 16:06:34
	System	03 Sep 2020 16:06:34

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:04:11', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2138d067-30c4-444f-a952-007639a06d60' User entered '98.2'	System	03 Sep 2020 16:06:34
	System	03 Sep 2020 16:06:34

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:04:15', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2138d067-30c4-444f-a952-007639a06d60' User entered 'No (N)'	System	03 Sep 2020 16:06:34
	System	03 Sep 2020 16:06:34

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:04:28', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2138d067-30c4-444f-a952-007639a06d60' User entered '03 Sep 2020 12:04'	System	03 Sep 2020 16:06:34
	System	03 Sep 2020 16:06:34

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Sep 2020 11:38'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Sep 2020 14:08'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:44:57', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4e52beec-bf52-4954-8996-f4af8e3fc4e0' User entered 'Yes (Y)'	System	03 Sep 2020 22:45:45
	System	03 Sep 2020 22:45:45

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:45:06', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4e52beec-bf52-4954-8996-f4af8e3fc4e0' User entered '97.6'	System	03 Sep 2020 22:45:45
	System	03 Sep 2020 22:45:45

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:45:11', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4e52beec-bf52-4954-8996-f4af8e3fc4e0'	System	03 Sep 2020 22:45:45
User entered 'No (N)'	System	03 Sep 2020 22:45:45

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:45:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4e52beec-bf52-4954-8996-f4af8e3fc4e0' User entered '03 Sep 2020 18:45'	System	03 Sep 2020 22:45:45
	System	03 Sep 2020 22:45:45

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Sep 2020 15:03'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 2'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:24:51', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7b744a31-f08a-40e4-b65c-ad0467dc02ce' User entered 'Yes (Y)'	System	05 Sep 2020 07:25:10
	System	05 Sep 2020 07:25:10

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:24:57', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7b744a31-f08a-40e4-b65c-ad0467dc02ce' User entered '98.0'	System	05 Sep 2020 07:25:10
	System	05 Sep 2020 07:25:10

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:25:01', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7b744a31-f08a-40e4-b65c-ad0467dc02ce'	System	05 Sep 2020 07:25:10
User entered 'No (N)'	System	05 Sep 2020 07:25:10

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:25:06', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7b744a31-f08a-40e4-b65c-ad0467dc02ce' User entered '05 Sep 2020 03:25'	System	05 Sep 2020 07:25:10
	System	05 Sep 2020 07:25:10

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 3'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:36:28', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '71b02092-ed36-410b-b891-316da7bf3bc6' User entered 'Yes (Y)'	System	05 Sep 2020 21:36:47
	System	05 Sep 2020 21:36:47

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:36:35', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '71b02092-ed36-410b-b891-316da7bf3bc6' User entered '97.7'	System	05 Sep 2020 21:36:47
	System	05 Sep 2020 21:36:47

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:36:38', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '71b02092-ed36-410b-b891-316da7bf3bc6'	System	05 Sep 2020 21:36:47
User entered 'No (N)'	System	05 Sep 2020 21:36:47

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:36:44', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '71b02092-ed36-410b-b891-316da7bf3bc6' User entered '05 Sep 2020 17:36'	System	05 Sep 2020 21:36:47
	System	05 Sep 2020 21:36:47

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 4'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:12:40', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b6282b44-1302-4ca7-b88c-671d4f76dd8b' User entered 'Yes (Y)'	System	06 Sep 2020 20:13:35
	System	06 Sep 2020 20:13:35

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:13:26', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b6282b44-1302-4ca7-b88c-671d4f76dd8b' User entered '97.5'	System	06 Sep 2020 20:13:35
	System	06 Sep 2020 20:13:35

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:13:29', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b6282b44-1302-4ca7-b88c-671d4f76dd8b' User entered 'No (N)'	System	06 Sep 2020 20:13:35
	System	06 Sep 2020 20:13:35

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:13:33', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b6282b44-1302-4ca7-b88c-671d4f76dd8b' User entered '06 Sep 2020 16:13'	System	06 Sep 2020 20:13:35
	System	06 Sep 2020 20:13:35

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 5'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:32:59', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '79437db8-43d9-4e33-8a20-68a9fbb41218' User entered 'Yes (Y)'	System	07 Sep 2020 18:33:17
	System	07 Sep 2020 18:33:17

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:33:06', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '79437db8-43d9-4e33-8a20-68a9fbb41218' User entered '97.8'	System	07 Sep 2020 18:33:17
	System	07 Sep 2020 18:33:17

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:33:10', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '79437db8-43d9-4e33-8a20-68a9fbb41218' User entered 'No (N)'	System	07 Sep 2020 18:33:17
	System	07 Sep 2020 18:33:17

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:33:14', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '79437db8-43d9-4e33-8a20-68a9fbb41218' User entered '07 Sep 2020 14:33'	System	07 Sep 2020 18:33:17
	System	07 Sep 2020 18:33:17

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 6'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:07:18', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7a63bbef-dbd0-49a9-a544-dbc43cc83929' User entered 'Yes (Y)'	System	08 Sep 2020 16:07:37
	System	08 Sep 2020 16:07:37

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:07:25', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7a63bbef-dbd0-49a9-a544-dbc43cc83929' User entered '97.8'	System	08 Sep 2020 16:07:37
	System	08 Sep 2020 16:07:37

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:07:28', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7a63bbef-dbd0-49a9-a544-dbc43cc83929' User entered 'No (N)'	System	08 Sep 2020 16:07:37
	System	08 Sep 2020 16:07:37

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:07:32', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7a63bbef-dbd0-49a9-a544-dbc43cc83929' User entered '08 Sep 2020 12:07'	System	08 Sep 2020 16:07:37
	System	08 Sep 2020 16:07:37

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 7'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:45', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7dbcc0e7-2533-47da-b367-e4ab23fc53c0' User entered 'Yes (Y)'	System	10 Sep 2020 13:00:30
	System	10 Sep 2020 13:00:30

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T09:00:19', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7dbcc0e7-2533-47da-b367-e4ab23fc53c0' User entered '97.4'	System	10 Sep 2020 13:00:30
	System	10 Sep 2020 13:00:30

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T09:00:22', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7dbcc0e7-2533-47da-b367-e4ab23fc53c0'	System	10 Sep 2020 13:00:30
User entered 'No (N)'	System	10 Sep 2020 13:00:30

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T09:00:25', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7dbcc0e7-2533-47da-b367-e4ab23fc53c0'	System	10 Sep 2020 13:00:30
User entered '10 Sep 2020 09:00'	System	10 Sep 2020 13:00:30

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:04:35', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd0812f8b-2fdb-49c7-b1b8-b998b1dfd172'	System	03 Sep 2020 16:07:07
User entered 'None (1)'	System	03 Sep 2020 16:07:07

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:04:55', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd0812f8b-2fdb-49c7-b1b8-b998b1dfd172'	System	03 Sep 2020 16:07:07
User entered 'No (N)'	System	03 Sep 2020 16:07:07

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:04:58', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd0812f8b-2fdb-49c7-b1b8-b998b1dfd172'	System	03 Sep 2020 16:07:07
User entered 'No (N)'	System	03 Sep 2020 16:07:07

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:05:12', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd0812f8b-2fdb-49c7-b1b8-b998b1dfd172'	System	03 Sep 2020 16:07:07
User entered 'None (1)'	System	03 Sep 2020 16:07:07

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:05:16', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd0812f8b-2fdb-49c7-b1b8-b998b1dfd172'	System	03 Sep 2020 16:07:07
User entered '03 Sep 2020 12:05'	System	03 Sep 2020 16:07:07

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Sep 2020 11:38'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Sep 2020 14:08'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:45:51', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '9e8d694d-5087-432a-8132-f418356fd216' User entered 'None (1)'	System	03 Sep 2020 22:46:52
	System	03 Sep 2020 22:46:52

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:46:21', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '9e8d694d-5087-432a-8132-f418356fd216' User entered 'No (N)'	System	03 Sep 2020 22:46:52
	System	03 Sep 2020 22:46:52

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:46:29', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '9e8d694d-5087-432a-8132-f418356fd216' User entered 'No (N)'	System	03 Sep 2020 22:46:52
	System	03 Sep 2020 22:46:52

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:46:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '9e8d694d-5087-432a-8132-f418356fd216'	System	03 Sep 2020 22:46:52
User entered 'None (1)'	System	03 Sep 2020 22:46:52

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:46:49', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '9e8d694d-5087-432a-8132-f418356fd216' User entered '03 Sep 2020 18:46'	System	03 Sep 2020 22:46:52
	System	03 Sep 2020 22:46:52

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Sep 2020 15:03'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 2'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:23', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'fcbaf538-a788-46e8-82d6-508c45202154'	System	05 Sep 2020 07:21:43
User entered 'None (1)'	System	05 Sep 2020 07:21:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:27', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'fcbaf538-a788-46e8-82d6-508c45202154'	System	05 Sep 2020 07:21:43
User entered 'No (N)'	System	05 Sep 2020 07:21:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:31', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'fcba538-a788-46e8-82d6-508c45202154'	System	05 Sep 2020 07:21:43
User entered 'No (N)'	System	05 Sep 2020 07:21:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:34', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'fcbaf538-a788-46e8-82d6-508c45202154' User entered 'None (1)'	System	05 Sep 2020 07:21:43
	System	05 Sep 2020 07:21:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:39', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'fcbaf538-a788-46e8-82d6-508c45202154' User entered '05 Sep 2020 03:21'	System	05 Sep 2020 07:21:43
	System	05 Sep 2020 07:21:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 3'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:36:49', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ee6def0a-7f0e-41e1-88c3-0fc701d3bedd' User entered 'None (1)'	System	05 Sep 2020 21:37:34
	System	05 Sep 2020 21:37:34

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:06', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ee6def0a-7f0e-41e1-88c3-0fc701d3bedd' User entered 'No (N)'	System	05 Sep 2020 21:37:34
	System	05 Sep 2020 21:37:34

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:16', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ee6def0a-7f0e-41e1-88c3-0fc701d3bedd' User entered 'No (N)'	System	05 Sep 2020 21:37:34
	System	05 Sep 2020 21:37:34

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:27', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ee6def0a-7f0e-41e1-88c3-0fc701d3bedd' User entered 'None (1)'	System	05 Sep 2020 21:37:34
	System	05 Sep 2020 21:37:34

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:32', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ee6def0a-7f0e-41e1-88c3-0fc701d3bedd' User entered '05 Sep 2020 17:37'	System	05 Sep 2020 21:37:34
	System	05 Sep 2020 21:37:34

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 4'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:11:48', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'f6298d55-c641-4dcf-a93f-44cedae5039a'	System	06 Sep 2020 20:12:05
User entered 'None (1)'	System	06 Sep 2020 20:12:05

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:11:52', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'f6298d55-c641-4dcf-a93f-44cedae5039a' User entered 'No (N)'	System	06 Sep 2020 20:12:05
	System	06 Sep 2020 20:12:05

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:11:55', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'f6298d55-c641-4dcf-a93f-44cedae5039a' User entered 'No (N)'	System	06 Sep 2020 20:12:05
	System	06 Sep 2020 20:12:05

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:11:57', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'f6298d55-c641-4dcf-a93f-44cedae5039a' User entered 'None (1)'	System	06 Sep 2020 20:12:05
	System	06 Sep 2020 20:12:05

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:12:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'f6298d55-c641-4dcf-a93f-44cedae5039a' User entered '06 Sep 2020 16:12'	System	06 Sep 2020 20:12:05
	System	06 Sep 2020 20:12:05

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 5'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:33:46', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d504278-1406-4236-b073-00fa0ddb04e1'	System	07 Sep 2020 18:34:04
User entered 'None (1)'	System	07 Sep 2020 18:34:04

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:33:49', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d504278-1406-4236-b073-00fa0ddb04e1' User entered 'No (N)'	System	07 Sep 2020 18:34:04
	System	07 Sep 2020 18:34:04

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:33:53', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d504278-1406-4236-b073-00fa0ddb04e1' User entered 'No (N)'	System	07 Sep 2020 18:34:04
	System	07 Sep 2020 18:34:04

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:33:55', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d504278-1406-4236-b073-00fa0ddb04e1' User entered 'None (1)'	System	07 Sep 2020 18:34:04
	System	07 Sep 2020 18:34:04

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:34:03', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d504278-1406-4236-b073-00fa0ddb04e1' User entered '07 Sep 2020 14:34'	System	07 Sep 2020 18:34:04
	System	07 Sep 2020 18:34:04

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 6'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:03:58', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4f9cbc65-2c5d-4220-84e0-3705a4e773c3'	System	08 Sep 2020 16:04:24
User entered 'None (1)'	System	08 Sep 2020 16:04:24

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:02', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4f9cbc65-2c5d-4220-84e0-3705a4e773c3' User entered 'No (N)'	System	08 Sep 2020 16:04:24
	System	08 Sep 2020 16:04:24

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:04', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4f9cbc65-2c5d-4220-84e0-3705a4e773c3' User entered 'No (N)'	System	08 Sep 2020 16:04:24
	System	08 Sep 2020 16:04:24

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:07', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4f9cbc65-2c5d-4220-84e0-3705a4e773c3'	System	08 Sep 2020 16:04:24
User entered 'None (1)'	System	08 Sep 2020 16:04:24

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:11', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4f9cbc65-2c5d-4220-84e0-3705a4e773c3' User entered '08 Sep 2020 12:04'	System	08 Sep 2020 16:04:24
	System	08 Sep 2020 16:04:24

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 7'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:27', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '197c8799-3a16-413a-9653-bf7b106b532a'	System	10 Sep 2020 12:58:40
User entered 'None (1)'	System	10 Sep 2020 12:58:40

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:29', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '197c8799-3a16-413a-9653-bf7b106b532a' User entered 'No (N)'	System	10 Sep 2020 12:58:40
	System	10 Sep 2020 12:58:40

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:32', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '197c8799-3a16-413a-9653-bf7b106b532a' User entered 'No (N)'	System	10 Sep 2020 12:58:40
	System	10 Sep 2020 12:58:40

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:35', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '197c8799-3a16-413a-9653-bf7b106b532a' User entered 'None (1)'	System	10 Sep 2020 12:58:40
	System	10 Sep 2020 12:58:40

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:39', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '197c8799-3a16-413a-9653-bf7b106b532a' User entered '10 Sep 2020 08:58'	System	10 Sep 2020 12:58:40
	System	10 Sep 2020 12:58:40

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:05:21', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '57c18cb8-354b-4576-8284-cd114cb490cc' User entered 'None (0)'	System	03 Sep 2020 16:07:21
	System	03 Sep 2020 16:07:21

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:05:23', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '57c18cb8-354b-4576-8284-cd114cb490cc' User entered 'None (0)'	System	03 Sep 2020 16:07:21
	System	03 Sep 2020 16:07:21

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:05:26', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '57c18cb8-354b-4576-8284-cd114cb490cc' User entered 'None (0)'	System	03 Sep 2020 16:07:21
	System	03 Sep 2020 16:07:21

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:05:29', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '57c18cb8-354b-4576-8284-cd114cb490cc' User entered 'None (0)'	System	03 Sep 2020 16:07:21
	System	03 Sep 2020 16:07:21

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:05:31', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '57c18cb8-354b-4576-8284-cd114cb490cc' User entered 'None (0)'	System	03 Sep 2020 16:07:21
	System	03 Sep 2020 16:07:21

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:05:34', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '57c18cb8-354b-4576-8284-cd114cb490cc' User entered 'None (0)'	System	03 Sep 2020 16:07:21
	System	03 Sep 2020 16:07:21

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:05:38', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '57c18cb8-354b-4576-8284-cd114cb490cc' User entered 'No (N)'	System	03 Sep 2020 16:07:21
	System	03 Sep 2020 16:07:21

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T12:05:41', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '57c18cb8-354b-4576-8284-cd114cb490cc' User entered '03 Sep 2020 12:05'	System	03 Sep 2020 16:07:21
	System	03 Sep 2020 16:07:21

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '03 Sep 2020 11:38'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '03 Sep 2020 14:08'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:46:54', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e80c4ebe-f525-4e1a-9cda-9930bcea7979' User entered 'None (0)'	System	03 Sep 2020 22:47:27
	System	03 Sep 2020 22:47:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:46:57', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e80c4ebe-f525-4e1a-9cda-9930bcea7979' User entered 'None (0)'	System	03 Sep 2020 22:47:27
	System	03 Sep 2020 22:47:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:47:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e80c4ebe-f525-4e1a-9cda-9930bcea7979' User entered 'None (0)'	System	03 Sep 2020 22:47:27
	System	03 Sep 2020 22:47:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:47:03', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e80c4ebe-f525-4e1a-9cda-9930bcea7979' User entered 'None (0)'	System	03 Sep 2020 22:47:27
	System	03 Sep 2020 22:47:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:47:05', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e80c4ebe-f525-4e1a-9cda-9930bcea7979' User entered 'None (0)'	System	03 Sep 2020 22:47:27
	System	03 Sep 2020 22:47:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:47:07', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e80c4ebe-f525-4e1a-9cda-9930bcea7979' User entered 'None (0)'	System	03 Sep 2020 22:47:27
	System	03 Sep 2020 22:47:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:47:15', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e80c4ebe-f525-4e1a-9cda-9930bcea7979' User entered 'No (N)'	System	03 Sep 2020 22:47:27
	System	03 Sep 2020 22:47:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-03T18:47:25', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e80c4ebe-f525-4e1a-9cda-9930bcea7979' User entered '03 Sep 2020 18:47'	System	03 Sep 2020 22:47:27
	System	03 Sep 2020 22:47:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '03 Sep 2020 15:03'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 2'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:44', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5a322ede-99ba-4c27-9c10-22de9e1867f3' User entered 'None (0)'	System	05 Sep 2020 07:22:03
	System	05 Sep 2020 07:22:03

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:46', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5a322ede-99ba-4c27-9c10-22de9e1867f3' User entered 'None (0)'	System	05 Sep 2020 07:22:03
	System	05 Sep 2020 07:22:03

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:48', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5a322ede-99ba-4c27-9c10-22de9e1867f3' User entered 'None (0)'	System	05 Sep 2020 07:22:03
	System	05 Sep 2020 07:22:03

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:50', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5a322ede-99ba-4c27-9c10-22de9e1867f3' User entered 'None (0)'	System	05 Sep 2020 07:22:03
	System	05 Sep 2020 07:22:03

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:52', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5a322ede-99ba-4c27-9c10-22de9e1867f3' User entered 'None (0)'	System	05 Sep 2020 07:22:03
	System	05 Sep 2020 07:22:03

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:54', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5a322ede-99ba-4c27-9c10-22de9e1867f3' User entered 'None (0)'	System	05 Sep 2020 07:22:03
	System	05 Sep 2020 07:22:03

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:21:59', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5a322ede-99ba-4c27-9c10-22de9e1867f3' User entered 'No (N)'	System	05 Sep 2020 07:22:03
	System	05 Sep 2020 07:22:03

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T03:22:01', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5a322ede-99ba-4c27-9c10-22de9e1867f3' User entered '05 Sep 2020 03:22'	System	05 Sep 2020 07:22:03
	System	05 Sep 2020 07:22:03

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 3'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:36', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b2e2d82f-0ec2-4408-9bb6-843a3151852e' User entered 'None (0)'	System	05 Sep 2020 21:38:00
	System	05 Sep 2020 21:38:00

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:38', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b2e2d82f-0ec2-4408-9bb6-843a3151852e' User entered 'None (0)'	System	05 Sep 2020 21:38:00
	System	05 Sep 2020 21:38:00

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:40', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b2e2d82f-0ec2-4408-9bb6-843a3151852e' User entered 'None (0)'	System	05 Sep 2020 21:38:00
	System	05 Sep 2020 21:38:00

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:42', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b2e2d82f-0ec2-4408-9bb6-843a3151852e' User entered 'None (0)'	System	05 Sep 2020 21:38:00
	System	05 Sep 2020 21:38:00

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:44', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b2e2d82f-0ec2-4408-9bb6-843a3151852e' User entered 'None (0)'	System	05 Sep 2020 21:38:00
	System	05 Sep 2020 21:38:00

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:46', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b2e2d82f-0ec2-4408-9bb6-843a3151852e' User entered 'None (0)'	System	05 Sep 2020 21:38:00
	System	05 Sep 2020 21:38:00

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:52', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b2e2d82f-0ec2-4408-9bb6-843a3151852e' User entered 'No (N)'	System	05 Sep 2020 21:38:00
	System	05 Sep 2020 21:38:00

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-05T17:37:57', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b2e2d82f-0ec2-4408-9bb6-843a3151852e' User entered '05 Sep 2020 17:37'	System	05 Sep 2020 21:38:00
	System	05 Sep 2020 21:38:00

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 4'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:12:04', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68deb091-6e4d-47c9-83f8-5c690731874f' User entered 'None (0)'	System	06 Sep 2020 20:12:23
	System	06 Sep 2020 20:12:23

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:12:06', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68deb091-6e4d-47c9-83f8-5c690731874f' User entered 'None (0)'	System	06 Sep 2020 20:12:23
	System	06 Sep 2020 20:12:23

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:12:08', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68deb091-6e4d-47c9-83f8-5c690731874f' User entered 'None (0)'	System	06 Sep 2020 20:12:23
	System	06 Sep 2020 20:12:23

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:12:10', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68deb091-6e4d-47c9-83f8-5c690731874f' User entered 'None (0)'	System	06 Sep 2020 20:12:23
	System	06 Sep 2020 20:12:23

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:12:12', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68deb091-6e4d-47c9-83f8-5c690731874f' User entered 'None (0)'	System	06 Sep 2020 20:12:23
	System	06 Sep 2020 20:12:23

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:12:14', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68deb091-6e4d-47c9-83f8-5c690731874f' User entered 'None (0)'	System	06 Sep 2020 20:12:23
	System	06 Sep 2020 20:12:23

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:12:17', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68deb091-6e4d-47c9-83f8-5c690731874f' User entered 'No (N)'	System	06 Sep 2020 20:12:23
	System	06 Sep 2020 20:12:23

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-06T16:12:20', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68deb091-6e4d-47c9-83f8-5c690731874f' User entered '06 Sep 2020 16:12'	System	06 Sep 2020 20:12:23
	System	06 Sep 2020 20:12:23

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 5'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:34:06', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '371e5fe6-13c4-47c9-9fc6-9cb036820258' User entered 'None (0)'	System	07 Sep 2020 18:34:30
	System	07 Sep 2020 18:34:30

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:34:08', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '371e5fe6-13c4-47c9-9fc6-9cb036820258' User entered 'None (0)'	System	07 Sep 2020 18:34:30
	System	07 Sep 2020 18:34:30

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:34:10', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '371e5fe6-13c4-47c9-9fc6-9cb036820258' User entered 'None (0)'	System	07 Sep 2020 18:34:30
	System	07 Sep 2020 18:34:30

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:34:12', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '371e5fe6-13c4-47c9-9fc6-9cb036820258' User entered 'None (0)'	System	07 Sep 2020 18:34:30
	System	07 Sep 2020 18:34:30

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:34:14', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '371e5fe6-13c4-47c9-9fc6-9cb036820258' User entered 'None (0)'	System	07 Sep 2020 18:34:30
	System	07 Sep 2020 18:34:30

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:34:16', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '371e5fe6-13c4-47c9-9fc6-9cb036820258' User entered 'None (0)'	System	07 Sep 2020 18:34:30
	System	07 Sep 2020 18:34:30

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:34:19', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '371e5fe6-13c4-47c9-9fc6-9cb036820258' User entered 'No (N)'	System	07 Sep 2020 18:34:30
	System	07 Sep 2020 18:34:30

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-07T14:34:26', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '371e5fe6-13c4-47c9-9fc6-9cb036820258' User entered '07 Sep 2020 14:34'	System	07 Sep 2020 18:34:30
	System	07 Sep 2020 18:34:30

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 6'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:15', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '31ca6a8a-d9c8-476d-9501-1f51c15890b6' User entered 'None (0)'	System	08 Sep 2020 16:04:40
	System	08 Sep 2020 16:04:40

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:17', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '31ca6a8a-d9c8-476d-9501-1f51c15890b6' User entered 'None (0)'	System	08 Sep 2020 16:04:40
	System	08 Sep 2020 16:04:40

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:19', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '31ca6a8a-d9c8-476d-9501-1f51c15890b6' User entered 'None (0)'	System	08 Sep 2020 16:04:40
	System	08 Sep 2020 16:04:40

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:21', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '31ca6a8a-d9c8-476d-9501-1f51c15890b6' User entered 'None (0)'	System	08 Sep 2020 16:04:40
	System	08 Sep 2020 16:04:40

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:23', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '31ca6a8a-d9c8-476d-9501-1f51c15890b6' User entered 'None (0)'	System	08 Sep 2020 16:04:40
	System	08 Sep 2020 16:04:40

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:25', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '31ca6a8a-d9c8-476d-9501-1f51c15890b6' User entered 'None (0)'	System	08 Sep 2020 16:04:40
	System	08 Sep 2020 16:04:40

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:28', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '31ca6a8a-d9c8-476d-9501-1f51c15890b6' User entered 'No (N)'	System	08 Sep 2020 16:04:40
	System	08 Sep 2020 16:04:40

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-08T12:04:36', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '31ca6a8a-d9c8-476d-9501-1f51c15890b6' User entered '08 Sep 2020 12:04'	System	08 Sep 2020 16:04:40
	System	08 Sep 2020 16:04:40

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 7'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:05', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4bb94f4c-2d07-4af3-8ebc-089a418adcfd' User entered 'None (0)'	System	10 Sep 2020 12:58:27
	System	10 Sep 2020 12:58:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:07', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4bb94f4c-2d07-4af3-8ebc-089a418adcfd' User entered 'None (0)'	System	10 Sep 2020 12:58:27
	System	10 Sep 2020 12:58:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:09', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4bb94f4c-2d07-4af3-8ebc-089a418adcfd' User entered 'None (0)'	System	10 Sep 2020 12:58:27
	System	10 Sep 2020 12:58:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:10', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4bb94f4c-2d07-4af3-8ebc-089a418adcfd' User entered 'None (0)'	System	10 Sep 2020 12:58:27
	System	10 Sep 2020 12:58:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:12', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4bb94f4c-2d07-4af3-8ebc-089a418adcfd' User entered 'None (0)'	System	10 Sep 2020 12:58:27
	System	10 Sep 2020 12:58:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:14', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4bb94f4c-2d07-4af3-8ebc-089a418adcfd' User entered 'None (0)'	System	10 Sep 2020 12:58:27
	System	10 Sep 2020 12:58:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:17', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4bb94f4c-2d07-4af3-8ebc-089a418adcfd' User entered 'No (N)'	System	10 Sep 2020 12:58:27
	System	10 Sep 2020 12:58:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-10T08:58:23', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4bb94f4c-2d07-4af3-8ebc-089a418adcfd' User entered '10 Sep 2020 08:58'	System	10 Sep 2020 12:58:27
	System	10 Sep 2020 12:58:27

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 15:29:43

US3742229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:18
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 14:59:10

US3742229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 14:59:10

US3742229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 14:59:10

US3742229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Sep 2020 14:59:10

US3742229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 14:59:20

US3742229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'I'	System	12 Sep 2020 14:59:20

US3742229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Sep 2020 19:25:35

US3742229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '17 Sep 2020'	Sherry McCammon (b) (4)	17 Sep 2020 19:25:35

US3742229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	17 Sep 2020 19:25:35

US3742229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Sherry McCammon (b) (4)	17 Sep 2020 19:25:35

US3742229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Sep 2020 19:25:59

US3742229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'I'	System	17 Sep 2020 19:25:59

US3742229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:00:36

US3742229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:00:36

US3742229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:00:36

US3742229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:00:36

US3742229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 20:00:42

US3742229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'I'	System	24 Sep 2020 20:00:42

US3742229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 19:54:37

US3742229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '30 Sep 2020'	(b) (4) Sherry McCammon (b) (4)	30 Sep 2020 19:54:37

US3742229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	30 Sep 2020 19:54:37

US3742229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'VISIT2'	System	30 Sep 2020 19:54:37

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43
	(b) (4)	

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '30 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '11:25'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '30 Sep 2020 11:25'	System	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '098.1' F	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '075'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'bpm'	System	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '14'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'breaths/min'	System	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '130'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'mmHg'	System	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '080'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:30:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'mmHg'	System	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43
	(b) (4)	

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '30 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '12:36'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '30 Sep 2020 12:36'	System	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '098.0' F	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '082'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'bpm'	System	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '14'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'breaths/min'	System	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '122'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'mmHg'	System	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '077'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:30:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'mmHg'	System	30 Sep 2020 19:57:43

US3742229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:30

US3742229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '30 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:30

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:09:05

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:09:05

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

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)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:09:05

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'MRNA-1273 OR PLACEBO'	System	30 Sep 2020 16:09:05

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:09:05

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '12:06'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:09:05

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '30 Sep 2020 12:06'	System	30 Sep 2020 16:09:05

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:09:05

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'ONCE'	System	30 Sep 2020 16:09:05

US3742229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:30:51

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'INTRAMUSCULAR'	System	30 Sep 2020 16:09:05

US3742229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:59

US3742229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '30 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:59

US3742229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '11:18'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:59

US3742229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '30 Sep 2020 11:18'	System	30 Sep 2020 19:58:59

US3742229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:30:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '30 Sep 2020'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:45

US3742229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:45

US3742229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:45

US3742229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '11:17'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:45

US3742229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '30 Sep 2020 11:17'	System	30 Sep 2020 19:58:45

US3742229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:51

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:45

US3742229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	Sherry McCammon (b) (4)	30 Sep 2020 19:58:45

US3742229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Sherry McCammon (b) (4)	30 Sep 2020 19:58:45

US3742229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered empty.	System	30 Sep 2020 19:58:45

US3742229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	30 Sep 2020 19:57:53

US3742229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '1'	System	30 Sep 2020 19:57:53

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:39:03', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd2f67789-9a13-494b-8ebc-ef3cca22a5e5'	System	30 Sep 2020 16:39:32
User entered 'Yes (Y)'	System	30 Sep 2020 16:39:32

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:39:13', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd2f67789-9a13-494b-8ebc-ef3cca22a5e5' User entered '98.0'	System	30 Sep 2020 16:39:32
	System	30 Sep 2020 16:39:32

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:39:18', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd2f67789-9a13-494b-8ebc-ef3cca22a5e5'	System	30 Sep 2020 16:39:32
User entered 'No (N)'	System	30 Sep 2020 16:39:32

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:39:27', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd2f67789-9a13-494b-8ebc-ef3cca22a5e5'	System	30 Sep 2020 16:39:32
User entered '30 Sep 2020 12:39'	System	30 Sep 2020 16:39:32

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '30 Sep 2020 12:26'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '30 Sep 2020 14:56'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:32:31', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '3f945d8c-3213-4f68-87c5-51540bcd2000'	System	01 Oct 2020 13:33:14
User entered 'Yes (Y)'	System	01 Oct 2020 13:33:14

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:32:40', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '3f945d8c-3213-4f68-87c5-51540bcd2000' User entered '98.2'	System	01 Oct 2020 13:33:14
	System	01 Oct 2020 13:33:14

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:32:47', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '3f945d8c-3213-4f68-87c5-51540bcd2000'	System	01 Oct 2020 13:33:14
User entered 'Yes (Y)'	System	01 Oct 2020 13:33:14

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'ALEVE 1 TAB AND IBUPROFEN 200 MG ALTERNATED FOR PAIN AND FEVER' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 09:49:28
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 15:45:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:32:58', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '3f945d8c-3213-4f68-87c5-51540bcd2000'	System	01 Oct 2020 13:33:14
User entered '1'	System	01 Oct 2020 13:33:14

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:32:58', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '3f945d8c-3213-4f68-87c5-51540bcd2000' User entered '0'	System	01 Oct 2020 13:33:14
	System	01 Oct 2020 13:33:14

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:33:07', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '3f945d8c-3213-4f68-87c5-51540bcd2000'	System	01 Oct 2020 13:33:14
User entered '01 Oct 2020 09:33'	System	01 Oct 2020 13:33:14

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '30 Sep 2020 15:51'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 2'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:39:05', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '8d05f87a-7829-43b2-a3bf-d45c554b294d' User entered 'Yes (Y)'	System	01 Oct 2020 21:39:45
	System	01 Oct 2020 21:39:45

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:39:16', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '8d05f87a-7829-43b2-a3bf-d45c554b294d' User entered '98.9'	System	01 Oct 2020 21:39:45
	System	01 Oct 2020 21:39:45

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:39:29', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '8d05f87a-7829-43b2-a3bf-d45c554b294d'	System	01 Oct 2020 21:39:45
User entered 'Yes (Y)'	System	01 Oct 2020 21:39:45

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'ALEVE 1 TAB AND IBUPROFEN 200 MG ALTERNATED FOR PAIN AND FEVER' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 09:49:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 15:44:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:39:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '8d05f87a-7829-43b2-a3bf-d45c554b294d'	System	01 Oct 2020 21:39:45
User entered '1'	System	01 Oct 2020 21:39:45

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:39:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '8d05f87a-7829-43b2-a3bf-d45c554b294d' User entered '0'	System	01 Oct 2020 21:39:45
	System	01 Oct 2020 21:39:45

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:39:43', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '8d05f87a-7829-43b2-a3bf-d45c554b294d' User entered '01 Oct 2020 17:39'	System	01 Oct 2020 21:39:45
	System	01 Oct 2020 21:39:45

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 3'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:02:18', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68b2586a-b11a-4416-a752-ee6d0e4972fd' User entered 'Yes (Y)'	System	02 Oct 2020 23:02:47
	System	02 Oct 2020 23:02:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:02:30', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68b2586a-b11a-4416-a752-ee6d0e4972fd' User entered '97.4'	System	02 Oct 2020 23:02:47
	System	02 Oct 2020 23:02:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:02:33', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68b2586a-b11a-4416-a752-ee6d0e4972fd' User entered 'No (N)'	System	02 Oct 2020 23:02:47
	System	02 Oct 2020 23:02:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:02:44', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '68b2586a-b11a-4416-a752-ee6d0e4972fd' User entered '02 Oct 2020 19:02'	System	02 Oct 2020 23:02:47
	System	02 Oct 2020 23:02:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 4'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:48:43', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5ccaf3f8-bbd4-4eeb-93b1-21c750added3' User entered 'Yes (Y)'	System	04 Oct 2020 00:48:59
	System	04 Oct 2020 00:48:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:48:50', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5ccaf3f8-bbd4-4eeb-93b1-21c750added3' User entered '97.7'	System	04 Oct 2020 00:48:59
	System	04 Oct 2020 00:48:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:48:53', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5ccaf3f8-bbd4-4eeb-93b1-21c750added3' User entered 'No (N)'	System	04 Oct 2020 00:48:59
	System	04 Oct 2020 00:48:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:48:58', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '5ccaf3f8-bbd4-4eeb-93b1-21c750added3' User entered '03 Oct 2020 20:48'	System	04 Oct 2020 00:48:59
	System	04 Oct 2020 00:48:59

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 5'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:18:27', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2d353de1-76ef-436f-b44f-15f84598d4b9' User entered 'Yes (Y)'	System	04 Oct 2020 19:18:47
	System	04 Oct 2020 19:18:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:18:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2d353de1-76ef-436f-b44f-15f84598d4b9' User entered '97.5'	System	04 Oct 2020 19:18:47
	System	04 Oct 2020 19:18:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:18:39', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2d353de1-76ef-436f-b44f-15f84598d4b9' User entered 'No (N)'	System	04 Oct 2020 19:18:47
	System	04 Oct 2020 19:18:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:18:44', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2d353de1-76ef-436f-b44f-15f84598d4b9' User entered '04 Oct 2020 15:18'	System	04 Oct 2020 19:18:47
	System	04 Oct 2020 19:18:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 6'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:12', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'af841a4e-bf28-4859-b4e3-5a570466ab22'	System	06 Oct 2020 04:03:33
User entered 'Yes (Y)'	System	06 Oct 2020 04:03:33

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:25', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'af841a4e-bf28-4859-b4e3-5a570466ab22' User entered '97.3'	System	06 Oct 2020 04:03:33
	System	06 Oct 2020 04:03:33

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:27', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'af841a4e-bf28-4859-b4e3-5a570466ab22'	System	06 Oct 2020 04:03:33
User entered 'No (N)'	System	06 Oct 2020 04:03:33

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:31', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'af841a4e-bf28-4859-b4e3-5a570466ab22' User entered '06 Oct 2020 00:03'	System	06 Oct 2020 04:03:33
	System	06 Oct 2020 04:03:33

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 7'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:48:35', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b28ecb25-ec64-427f-adcf-210580b6598c' User entered 'Yes (Y)'	System	07 Oct 2020 01:55:31
	System	07 Oct 2020 01:55:31

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:55:08', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b28ecb25-ec64-427f-adcf-210580b6598c' User entered '97.2'	System	07 Oct 2020 01:55:31
	System	07 Oct 2020 01:55:31

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:55:14', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b28ecb25-ec64-427f-adcf-210580b6598c'	System	07 Oct 2020 01:55:31
User entered 'Yes (Y)'	System	07 Oct 2020 01:55:31

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'ADVIL 1 TAB FOR HEADACHE' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 09:49:44
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 15:48:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:55:20', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b28ecb25-ec64-427f-adcf-210580b6598c'	System	07 Oct 2020 01:55:31
User entered '1'	System	07 Oct 2020 01:55:31

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:55:20', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b28ecb25-ec64-427f-adcf-210580b6598c' User entered '0'	System	07 Oct 2020 01:55:31
	System	07 Oct 2020 01:55:31

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:55:29', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b28ecb25-ec64-427f-adcf-210580b6598c'	System	07 Oct 2020 01:55:31
User entered '06 Oct 2020 21:55'	System	07 Oct 2020 01:55:31

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	07 Oct 2020 01:55:31
User entered 'Day 8'	System	07 Oct 2020 01:55:31

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:30:51

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-07T12:09:19', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4ec03d22-83ef-47df-906f-2c9735a8fa60' User entered 'Yes (Y)'	System	07 Oct 2020 16:10:47
	System	07 Oct 2020 16:10:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:30:51

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-07T12:10:33', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4ec03d22-83ef-47df-906f-2c9735a8fa60' User entered '97.2'	System	07 Oct 2020 16:10:47
	System	07 Oct 2020 16:10:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-07T12:10:39', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4ec03d22-83ef-47df-906f-2c9735a8fa60'	System	07 Oct 2020 16:10:47
User entered 'No (N)'	System	07 Oct 2020 16:10:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-07T12:10:45', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '4ec03d22-83ef-47df-906f-2c9735a8fa60' User entered '07 Oct 2020 12:10'	System	07 Oct 2020 16:10:47
	System	07 Oct 2020 16:10:47

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 01:55:31

US3742229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 01:55:31

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:40:25', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1f2895e1-d4e6-4548-a133-30724f4d366c'	System	30 Sep 2020 16:40:47
User entered 'None (1)'	System	30 Sep 2020 16:40:47

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:40:29', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1f2895e1-d4e6-4548-a133-30724f4d366c'	System	30 Sep 2020 16:40:47
User entered 'No (N)'	System	30 Sep 2020 16:40:47

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:40:32', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1f2895e1-d4e6-4548-a133-30724f4d366c' User entered 'No (N)'	System	30 Sep 2020 16:40:47
	System	30 Sep 2020 16:40:47

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:40:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1f2895e1-d4e6-4548-a133-30724f4d366c' User entered 'None (1)'	System	30 Sep 2020 16:40:47
	System	30 Sep 2020 16:40:47

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:40:44', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1f2895e1-d4e6-4548-a133-30724f4d366c' User entered '30 Sep 2020 12:40'	System	30 Sep 2020 16:40:47
	System	30 Sep 2020 16:40:47

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '30 Sep 2020 12:26'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '30 Sep 2020 14:56'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:34:07', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '978300c4-eec8-4838-9b9f-6e35441113c0'	System	01 Oct 2020 13:34:50
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 13:34:50

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:34:11', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '978300c4-eec8-4838-9b9f-6e35441113c0' User entered 'No (N)'	System	01 Oct 2020 13:34:50
	System	01 Oct 2020 13:34:50

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:34:27', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '978300c4-eec8-4838-9b9f-6e35441113c0' User entered 'No (N)'	System	01 Oct 2020 13:34:50
	System	01 Oct 2020 13:34:50

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:34:34', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '978300c4-eec8-4838-9b9f-6e35441113c0'	System	01 Oct 2020 13:34:50
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 13:34:50

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:34:47', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '978300c4-eec8-4838-9b9f-6e35441113c0' User entered '01 Oct 2020 09:34'	System	01 Oct 2020 13:34:50
	System	01 Oct 2020 13:34:50

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '30 Sep 2020 15:51'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 2'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:39:48', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '70210cf6-0cc4-4796-9737-b8d66bc10772'	System	01 Oct 2020 21:42:22
User entered 'None (1)'	System	01 Oct 2020 21:42:22

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:42:01', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '70210cf6-0cc4-4796-9737-b8d66bc10772' User entered 'No (N)'	System	01 Oct 2020 21:42:22
	System	01 Oct 2020 21:42:22

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:42:03', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '70210cf6-0cc4-4796-9737-b8d66bc10772'	System	01 Oct 2020 21:42:22
User entered 'No (N)'	System	01 Oct 2020 21:42:22

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:42:11', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '70210cf6-0cc4-4796-9737-b8d66bc10772'	System	01 Oct 2020 21:42:22
User entered 'None (1)'	System	01 Oct 2020 21:42:22

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:42:21', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '70210cf6-0cc4-4796-9737-b8d66bc10772'	System	01 Oct 2020 21:42:22
User entered '01 Oct 2020 17:42'	System	01 Oct 2020 21:42:22

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 3'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:02:49', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b5600f1e-8aa7-4912-a029-9359fa9c871b' User entered 'None (1)'	System	02 Oct 2020 23:03:08
	System	02 Oct 2020 23:03:08

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:02:52', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b5600f1e-8aa7-4912-a029-9359fa9c871b' User entered 'No (N)'	System	02 Oct 2020 23:03:08
	System	02 Oct 2020 23:03:08

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:02:55', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b5600f1e-8aa7-4912-a029-9359fa9c871b' User entered 'No (N)'	System	02 Oct 2020 23:03:08
	System	02 Oct 2020 23:03:08

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:02:58', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b5600f1e-8aa7-4912-a029-9359fa9c871b' User entered 'None (1)'	System	02 Oct 2020 23:03:08
	System	02 Oct 2020 23:03:08

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:03:06', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b5600f1e-8aa7-4912-a029-9359fa9c871b' User entered '02 Oct 2020 19:03'	System	02 Oct 2020 23:03:08
	System	02 Oct 2020 23:03:08

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 4'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:02', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2e00da8a-5e84-42a4-966e-1c90d973dd8b' User entered 'None (1)'	System	04 Oct 2020 00:49:21
	System	04 Oct 2020 00:49:21

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:05', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2e00da8a-5e84-42a4-966e-1c90d973dd8b' User entered 'No (N)'	System	04 Oct 2020 00:49:21
	System	04 Oct 2020 00:49:21

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:08', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2e00da8a-5e84-42a4-966e-1c90d973dd8b' User entered 'No (N)'	System	04 Oct 2020 00:49:21
	System	04 Oct 2020 00:49:21

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:11', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2e00da8a-5e84-42a4-966e-1c90d973dd8b' User entered 'None (1)'	System	04 Oct 2020 00:49:21
	System	04 Oct 2020 00:49:21

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:17', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2e00da8a-5e84-42a4-966e-1c90d973dd8b' User entered '03 Oct 2020 20:49'	System	04 Oct 2020 00:49:21
	System	04 Oct 2020 00:49:21

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 5'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:18:49', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0dcd41c2-2121-442a-bdd9-ed32994c453d'	System	04 Oct 2020 19:19:17
User entered 'None (1)'	System	04 Oct 2020 19:19:17

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:18:51', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0dcd41c2-2121-442a-bdd9-ed32994c453d' User entered 'No (N)'	System	04 Oct 2020 19:19:17
	System	04 Oct 2020 19:19:17

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:18:54', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0dcd41c2-2121-442a-bdd9-ed32994c453d' User entered 'No (N)'	System	04 Oct 2020 19:19:17
	System	04 Oct 2020 19:19:17

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:18:58', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0dcd41c2-2121-442a-bdd9-ed32994c453d'	System	04 Oct 2020 19:19:17
User entered 'None (1)'	System	04 Oct 2020 19:19:17

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:19:04', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0dcd41c2-2121-442a-bdd9-ed32994c453d' User entered '04 Oct 2020 15:19'	System	04 Oct 2020 19:19:17
	System	04 Oct 2020 19:19:17

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 6'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:35', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0d79cefa-9c8b-4da1-9f79-d90b8999e699'	System	06 Oct 2020 04:03:52
User entered 'None (1)'	System	06 Oct 2020 04:03:52

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:38', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0d79cefa-9c8b-4da1-9f79-d90b8999e699'	System	06 Oct 2020 04:03:52
User entered 'No (N)'	System	06 Oct 2020 04:03:52

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:41', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0d79cefa-9c8b-4da1-9f79-d90b8999e699' User entered 'No (N)'	System	06 Oct 2020 04:03:52
	System	06 Oct 2020 04:03:52

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:45', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0d79cefa-9c8b-4da1-9f79-d90b8999e699'	System	06 Oct 2020 04:03:52
User entered 'None (1)'	System	06 Oct 2020 04:03:52

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:50', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0d79cefa-9c8b-4da1-9f79-d90b8999e699' User entered '06 Oct 2020 00:03'	System	06 Oct 2020 04:03:52
	System	06 Oct 2020 04:03:52

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 7'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:48:10', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '01bb5b30-e078-46fd-a030-24fec660f169'	System	07 Oct 2020 01:48:28
User entered 'None (1)'	System	07 Oct 2020 01:48:28

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:48:13', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '01bb5b30-e078-46fd-a030-24fec660f169' User entered 'No (N)'	System	07 Oct 2020 01:48:28
	System	07 Oct 2020 01:48:28

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:48:16', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '01bb5b30-e078-46fd-a030-24fec660f169' User entered 'No (N)'	System	07 Oct 2020 01:48:28
	System	07 Oct 2020 01:48:28

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:48:19', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '01bb5b30-e078-46fd-a030-24fec660f169'	System	07 Oct 2020 01:48:28
User entered 'None (1)'	System	07 Oct 2020 01:48:28

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:48:26', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '01bb5b30-e078-46fd-a030-24fec660f169' User entered '06 Oct 2020 21:48'	System	07 Oct 2020 01:48:28
	System	07 Oct 2020 01:48:28

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:40:49', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '46602241-13bc-4376-83f6-33f1c60666b7' User entered 'None (0)'	System	30 Sep 2020 16:41:15
	System	30 Sep 2020 16:41:15

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:40:52', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '46602241-13bc-4376-83f6-33f1c60666b7' User entered 'None (0)'	System	30 Sep 2020 16:41:15
	System	30 Sep 2020 16:41:15

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:40:54', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '46602241-13bc-4376-83f6-33f1c60666b7' User entered 'None (0)'	System	30 Sep 2020 16:41:15
	System	30 Sep 2020 16:41:15

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:40:56', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '46602241-13bc-4376-83f6-33f1c60666b7' User entered 'None (0)'	System	30 Sep 2020 16:41:15
	System	30 Sep 2020 16:41:15

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:40:59', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '46602241-13bc-4376-83f6-33f1c60666b7' User entered 'None (0)'	System	30 Sep 2020 16:41:15
	System	30 Sep 2020 16:41:15

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:41:01', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '46602241-13bc-4376-83f6-33f1c60666b7' User entered 'None (0)'	System	30 Sep 2020 16:41:15
	System	30 Sep 2020 16:41:15

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:41:06', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '46602241-13bc-4376-83f6-33f1c60666b7' User entered 'No (N)'	System	30 Sep 2020 16:41:15
	System	30 Sep 2020 16:41:15

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-09-30T12:41:13', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '46602241-13bc-4376-83f6-33f1c60666b7' User entered '30 Sep 2020 12:41'	System	30 Sep 2020 16:41:15
	System	30 Sep 2020 16:41:15

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '30 Sep 2020 12:26'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '30 Sep 2020 14:56'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 1, after vaccination (at home)'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:35:04', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2494d9e0-58b1-4375-bd33-a933e0f4d252'	System	01 Oct 2020 13:36:56
User entered 'No interference with activity (1)'	System	01 Oct 2020 13:36:56

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:35:20', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2494d9e0-58b1-4375-bd33-a933e0f4d252'	System	01 Oct 2020 13:36:56
User entered 'Some interference with activity (2)'	System	01 Oct 2020 13:36:56

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:35:26', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2494d9e0-58b1-4375-bd33-a933e0f4d252'	System	01 Oct 2020 13:36:56
User entered 'Significant; prevents daily activity (3)'	System	01 Oct 2020 13:36:56

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:35:39', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2494d9e0-58b1-4375-bd33-a933e0f4d252'	System	01 Oct 2020 13:36:56
User entered 'Some interference with activity (2)'	System	01 Oct 2020 13:36:56

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:35:42', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2494d9e0-58b1-4375-bd33-a933e0f4d252' User entered 'None (0)'	System	01 Oct 2020 13:36:56
	System	01 Oct 2020 13:36:56

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:35:56', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2494d9e0-58b1-4375-bd33-a933e0f4d252'	System	01 Oct 2020 13:36:56
User entered 'Prevents daily activity and requires medical attention (3)'	System	01 Oct 2020 13:36:56

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:36:10', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2494d9e0-58b1-4375-bd33-a933e0f4d252' User entered 'No (N)'	System	01 Oct 2020 13:36:56
	System	01 Oct 2020 13:36:56

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T09:36:54', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '2494d9e0-58b1-4375-bd33-a933e0f4d252'	System	01 Oct 2020 13:36:56
User entered '01 Oct 2020 09:36'	System	01 Oct 2020 13:36:56

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '30 Sep 2020 15:51'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 2'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:38:34', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e0bdb93a-324d-42c3-b8f0-323fd12308bc' User entered 'None (0)'	System	01 Oct 2020 21:39:04
	System	01 Oct 2020 21:39:04

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:38:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e0bdb93a-324d-42c3-b8f0-323fd12308bc' User entered 'None (0)'	System	01 Oct 2020 21:39:04
	System	01 Oct 2020 21:39:04

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:38:39', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e0bdb93a-324d-42c3-b8f0-323fd12308bc' User entered 'None (0)'	System	01 Oct 2020 21:39:04
	System	01 Oct 2020 21:39:04

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:38:42', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e0bdb93a-324d-42c3-b8f0-323fd12308bc' User entered 'None (0)'	System	01 Oct 2020 21:39:04
	System	01 Oct 2020 21:39:04

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:38:45', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e0bdb93a-324d-42c3-b8f0-323fd12308bc' User entered 'None (0)'	System	01 Oct 2020 21:39:04
	System	01 Oct 2020 21:39:04

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:38:47', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e0bdb93a-324d-42c3-b8f0-323fd12308bc' User entered 'None (0)'	System	01 Oct 2020 21:39:04
	System	01 Oct 2020 21:39:04

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:38:51', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e0bdb93a-324d-42c3-b8f0-323fd12308bc' User entered 'No (N)'	System	01 Oct 2020 21:39:04
	System	01 Oct 2020 21:39:04

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-01T17:38:59', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e0bdb93a-324d-42c3-b8f0-323fd12308bc' User entered '01 Oct 2020 17:38'	System	01 Oct 2020 21:39:04
	System	01 Oct 2020 21:39:04

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 3'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:03:10', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '45a16ae9-803e-4791-891c-ee15b6deb09a' User entered 'None (0)'	System	02 Oct 2020 23:03:48
	System	02 Oct 2020 23:03:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:03:12', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '45a16ae9-803e-4791-891c-ee15b6deb09a' User entered 'None (0)'	System	02 Oct 2020 23:03:48
	System	02 Oct 2020 23:03:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:03:15', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '45a16ae9-803e-4791-891c-ee15b6deb09a' User entered 'None (0)'	System	02 Oct 2020 23:03:48
	System	02 Oct 2020 23:03:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:03:18', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '45a16ae9-803e-4791-891c-ee15b6deb09a' User entered 'None (0)'	System	02 Oct 2020 23:03:48
	System	02 Oct 2020 23:03:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:03:21', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '45a16ae9-803e-4791-891c-ee15b6deb09a' User entered 'None (0)'	System	02 Oct 2020 23:03:48
	System	02 Oct 2020 23:03:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:03:24', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '45a16ae9-803e-4791-891c-ee15b6deb09a' User entered 'None (0)'	System	02 Oct 2020 23:03:48
	System	02 Oct 2020 23:03:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:03:29', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '45a16ae9-803e-4791-891c-ee15b6deb09a' User entered 'No (N)'	System	02 Oct 2020 23:03:48
	System	02 Oct 2020 23:03:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-02T19:03:46', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '45a16ae9-803e-4791-891c-ee15b6deb09a' User entered '02 Oct 2020 19:03'	System	02 Oct 2020 23:03:48
	System	02 Oct 2020 23:03:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 4'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:22', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd555c977-048d-4530-8070-3cc99a6b19ec' User entered 'None (0)'	System	04 Oct 2020 00:49:48
	System	04 Oct 2020 00:49:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:24', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd555c977-048d-4530-8070-3cc99a6b19ec' User entered 'None (0)'	System	04 Oct 2020 00:49:48
	System	04 Oct 2020 00:49:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:26', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd555c977-048d-4530-8070-3cc99a6b19ec' User entered 'None (0)'	System	04 Oct 2020 00:49:48
	System	04 Oct 2020 00:49:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:29', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd555c977-048d-4530-8070-3cc99a6b19ec' User entered 'None (0)'	System	04 Oct 2020 00:49:48
	System	04 Oct 2020 00:49:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:32', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd555c977-048d-4530-8070-3cc99a6b19ec' User entered 'None (0)'	System	04 Oct 2020 00:49:48
	System	04 Oct 2020 00:49:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:34', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd555c977-048d-4530-8070-3cc99a6b19ec' User entered 'None (0)'	System	04 Oct 2020 00:49:48
	System	04 Oct 2020 00:49:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd555c977-048d-4530-8070-3cc99a6b19ec' User entered 'No (N)'	System	04 Oct 2020 00:49:48
	System	04 Oct 2020 00:49:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-03T20:49:45', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd555c977-048d-4530-8070-3cc99a6b19ec' User entered '03 Oct 2020 20:49'	System	04 Oct 2020 00:49:48
	System	04 Oct 2020 00:49:48

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '03 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '04 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 5'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:19:09', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d5f58c8-32f5-42ea-97cd-5e24927d2682' User entered 'None (0)'	System	04 Oct 2020 19:19:36
	System	04 Oct 2020 19:19:36

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:19:11', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d5f58c8-32f5-42ea-97cd-5e24927d2682' User entered 'None (0)'	System	04 Oct 2020 19:19:36
	System	04 Oct 2020 19:19:36

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:19:13', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d5f58c8-32f5-42ea-97cd-5e24927d2682' User entered 'None (0)'	System	04 Oct 2020 19:19:36
	System	04 Oct 2020 19:19:36

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:19:16', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d5f58c8-32f5-42ea-97cd-5e24927d2682' User entered 'None (0)'	System	04 Oct 2020 19:19:36
	System	04 Oct 2020 19:19:36

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:19:18', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d5f58c8-32f5-42ea-97cd-5e24927d2682' User entered 'None (0)'	System	04 Oct 2020 19:19:36
	System	04 Oct 2020 19:19:36

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:19:20', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d5f58c8-32f5-42ea-97cd-5e24927d2682' User entered 'None (0)'	System	04 Oct 2020 19:19:36
	System	04 Oct 2020 19:19:36

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:19:23', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d5f58c8-32f5-42ea-97cd-5e24927d2682' User entered 'No (N)'	System	04 Oct 2020 19:19:36
	System	04 Oct 2020 19:19:36

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-04T15:19:31', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '1d5f58c8-32f5-42ea-97cd-5e24927d2682' User entered '04 Oct 2020 15:19'	System	04 Oct 2020 19:19:36
	System	04 Oct 2020 19:19:36

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '04 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '05 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 6'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:54', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '49631c92-9155-461e-a23b-45fe3bb5bca4' User entered 'None (0)'	System	06 Oct 2020 04:04:17
	System	06 Oct 2020 04:04:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:56', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '49631c92-9155-461e-a23b-45fe3bb5bca4' User entered 'None (0)'	System	06 Oct 2020 04:04:17
	System	06 Oct 2020 04:04:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:03:58', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '49631c92-9155-461e-a23b-45fe3bb5bca4' User entered 'None (0)'	System	06 Oct 2020 04:04:17
	System	06 Oct 2020 04:04:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '49631c92-9155-461e-a23b-45fe3bb5bca4' User entered 'None (0)'	System	06 Oct 2020 04:04:17
	System	06 Oct 2020 04:04:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:04:02', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '49631c92-9155-461e-a23b-45fe3bb5bca4' User entered 'None (0)'	System	06 Oct 2020 04:04:17
	System	06 Oct 2020 04:04:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:04:04', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '49631c92-9155-461e-a23b-45fe3bb5bca4' User entered 'None (0)'	System	06 Oct 2020 04:04:17
	System	06 Oct 2020 04:04:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:04:07', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '49631c92-9155-461e-a23b-45fe3bb5bca4' User entered 'No (N)'	System	06 Oct 2020 04:04:17
	System	06 Oct 2020 04:04:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T00:04:14', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '49631c92-9155-461e-a23b-45fe3bb5bca4' User entered '06 Oct 2020 00:04'	System	06 Oct 2020 04:04:17
	System	06 Oct 2020 04:04:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '05 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '06 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	30 Sep 2020 16:09:05
User entered 'Day 7'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:47:40', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a5c3f538-6e9b-40ff-8600-31f932d1110b'	System	07 Oct 2020 01:48:17
User entered 'No interference with activity (1)'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:47:43', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a5c3f538-6e9b-40ff-8600-31f932d1110b' User entered 'None (0)'	System	07 Oct 2020 01:48:17
	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:47:46', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a5c3f538-6e9b-40ff-8600-31f932d1110b' User entered 'None (0)'	System	07 Oct 2020 01:48:17
	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:47:49', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a5c3f538-6e9b-40ff-8600-31f932d1110b' User entered 'None (0)'	System	07 Oct 2020 01:48:17
	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:47:52', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a5c3f538-6e9b-40ff-8600-31f932d1110b' User entered 'None (0)'	System	07 Oct 2020 01:48:17
	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:47:54', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a5c3f538-6e9b-40ff-8600-31f932d1110b' User entered 'None (0)'	System	07 Oct 2020 01:48:17
	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:47:57', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a5c3f538-6e9b-40ff-8600-31f932d1110b' User entered 'No (N)'	System	07 Oct 2020 01:48:17
	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-06T21:48:05', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a5c3f538-6e9b-40ff-8600-31f932d1110b' User entered '06 Oct 2020 21:48'	System	07 Oct 2020 01:48:17
	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '06 Oct 2020 12:00'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '07 Oct 2020 11:59'	System	30 Sep 2020 16:09:05

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	07 Oct 2020 01:48:17
User entered 'Day 8'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-07T12:11:31', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b92f8c49-7ce6-4d28-bee0-396bff798cb0'	System	07 Oct 2020 16:11:41
User entered 'No interference with activity (1)'	System	07 Oct 2020 16:11:41

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-07T12:11:36', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b92f8c49-7ce6-4d28-bee0-396bff798cb0' User entered '07 Oct 2020 12:11'	System	07 Oct 2020 16:11:41
	System	07 Oct 2020 16:11:41

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	07 Oct 2020 01:48:17
User entered 'Day 9'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-09T01:09:09', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '302f0c1c-7361-46d7-816d-a4acbc600a97' User entered 'None (0)'	System	09 Oct 2020 05:09:15
	System	09 Oct 2020 05:09:15

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:30:51

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-09T01:09:14', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '302f0c1c-7361-46d7-816d-a4acbc600a97' User entered '09 Oct 2020 01:09'	System	09 Oct 2020 05:09:15
	System	09 Oct 2020 05:09:15

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	07 Oct 2020 01:48:17
User entered 'Day 8'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-07T12:11:41', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '92b1ef3d-c5aa-4f50-b143-10bc005235e0' User entered 'No (N)'	System	07 Oct 2020 16:11:48
	System	07 Oct 2020 16:11:48

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-07T12:11:45', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '92b1ef3d-c5aa-4f50-b143-10bc005235e0' User entered '07 Oct 2020 12:11'	System	07 Oct 2020 16:11:48
	System	07 Oct 2020 16:11:48

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '07 Oct 2020 12:00'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	07 Oct 2020 01:48:17
User entered 'Day 9'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-09T01:09:20', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '01a2faac-1eae-4e3e-83fb-f5c8af4fd514'	System	09 Oct 2020 05:09:26
User entered 'No (N)'	System	09 Oct 2020 05:09:26

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:30:51

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-10-09T01:09:25', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '01a2faac-1eae-4e3e-83fb-f5c8af4fd514' User entered '09 Oct 2020 01:09'	System	09 Oct 2020 05:09:26
	System	09 Oct 2020 05:09:26

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:30:51

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 01:48:17

US3742229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:30:51

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 01:48:17

US3742229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:33:51

US3742229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:33:51

US3742229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:33:51

US3742229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:33:51

US3742229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:33:56

US3742229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'I'	System	08 Oct 2020 12:33:56

US3742229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	14 Oct 2020 19:58:56

US3742229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '14 Oct 2020'	Sherry McCammon (b) (4)	14 Oct 2020 19:58:56

US3742229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	14 Oct 2020 19:58:56

US3742229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Sherry McCammon (b) (4)	14 Oct 2020 19:58:56

US3742229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	14 Oct 2020 19:58:37

US3742229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'I'	System	14 Oct 2020 19:58:37

US3742229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 13:54:54

US3742229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '21 Oct 2020'	Sherry McCammon (b) (4)	23 Oct 2020 13:54:54

US3742229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	23 Oct 2020 13:54:54

US3742229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 13:54:54

US3742229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 13:55:01

US3742229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'I'	System	23 Oct 2020 13:55:01

US3742229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Hassan Haji (b) (4)	28 Oct 2020 15:43:30

US3742229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '28 Oct 2020'	Hassan Haji (b) (4)	28 Oct 2020 15:43:30

US3742229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	28 Oct 2020 15:43:30

US3742229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'VISIT3'	System	28 Oct 2020 15:43:30

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'No (N)'	Hassan Haji (b) (4)	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered empty.	System	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered empty.	System	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered empty.	System	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered empty.	System	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered empty.	System	28 Oct 2020 15:43:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:30:51

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43

US3742229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Hassan Haji (b) (4)	28 Oct 2020 15:43:52

US3742229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '28 Oct 2020'	Hassan Haji (b) (4)	28 Oct 2020 15:43:52

US3742229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Hassan Haji (b) (4)	28 Oct 2020 15:44:06

US3742229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '28 Oct 2020'	Hassan Haji (b) (4)	28 Oct 2020 15:44:06

US3742229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered '11:05'	Hassan Haji (b) (4)	28 Oct 2020 15:44:06

US3742229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '28 Oct 2020 11:05'	System	28 Oct 2020 15:44:06

US3742229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:34:44
User entered 'Yes (Y)'	Hassan Haji (b) (4)	28 Oct 2020 15:44:09

US3742229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered '1'	System	28 Oct 2020 15:44:09

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 64'	System	03 Sep 2020 15:29:43

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-03T04:51:59', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '50734c77-310b-4ba8-8871-a56b66e57c46'	System	03 Nov 2020 09:52:26
User entered 'No (N)'	System	03 Nov 2020 09:52:26

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-03T04:52:05', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '50734c77-310b-4ba8-8871-a56b66e57c46'	System	03 Nov 2020 09:52:26
User entered 'No (N)'	System	03 Nov 2020 09:52:26

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-03T04:52:22', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '50734c77-310b-4ba8-8871-a56b66e57c46' User entered '03 Nov 2020 04:52:22'	System	03 Nov 2020 09:52:26
	System	03 Nov 2020 09:52:26

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 15:29:43

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 71'	System	03 Sep 2020 15:29:43

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-12T09:25:45', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a4daa474-5e13-4802-aa1b-85a89560bfec' User entered 'No (N)'	System	12 Nov 2020 14:26:04
	System	12 Nov 2020 14:26:04

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-12T09:25:50', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a4daa474-5e13-4802-aa1b-85a89560bfec' User entered 'No (N)'	System	12 Nov 2020 14:26:04
	System	12 Nov 2020 14:26:04

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-12T09:26:01', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'a4daa474-5e13-4802-aa1b-85a89560bfec' User entered '12 Nov 2020 09:26:01'	System	12 Nov 2020 14:26:04
	System	12 Nov 2020 14:26:04

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 15:29:43

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered 'Day 78'	System	03 Sep 2020 15:29:43

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-17T01:31:42', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0233d79f-44d9-43ca-9109-10e3501fca72'	System	17 Nov 2020 06:31:58
User entered 'No (N)'	System	17 Nov 2020 06:31:58

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-17T01:31:46', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0233d79f-44d9-43ca-9109-10e3501fca72'	System	17 Nov 2020 06:31:58
User entered 'No (N)'	System	17 Nov 2020 06:31:58

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-17T01:31:54', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '0233d79f-44d9-43ca-9109-10e3501fca72' User entered '17 Nov 2020 01:31:54'	System	17 Nov 2020 06:31:58
	System	17 Nov 2020 06:31:58

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 15:29:43

US3742229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:12:26
Data entry locked.	System	03 Sep 2020 15:29:43
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 15:29:43

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-22T12:51:59', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'f8695f76-40a4-4ebc-bec1-af839843697f' User entered 'No (N)'	System	22 Nov 2020 17:52:11
	System	22 Nov 2020 17:52:11

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-22T12:52:03', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'f8695f76-40a4-4ebc-bec1-af839843697f' User entered 'No (N)'	System	22 Nov 2020 17:52:11
	System	22 Nov 2020 17:52:11

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-22T12:52:06', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'f8695f76-40a4-4ebc-bec1-af839843697f' User entered '22 Nov 2020 12:52:06'	System	22 Nov 2020 17:52:11
	System	22 Nov 2020 17:52:11

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-28T00:49:01', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c50f7229-f8ba-4e11-acdf-71ba664414de' User entered 'No (N)'	System	28 Nov 2020 05:49:15
	System	28 Nov 2020 05:49:15

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-28T00:49:06', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c50f7229-f8ba-4e11-acdf-71ba664414de'	System	28 Nov 2020 05:49:15
User entered 'No (N)'	System	28 Nov 2020 05:49:15

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-11-28T00:49:11', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c50f7229-f8ba-4e11-acdf-71ba664414de' User entered '28 Nov 2020 00:49:11'	System	28 Nov 2020 05:49:15
	System	28 Nov 2020 05:49:15

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-05T02:18:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c5270903-1c05-4560-85dc-23410817da2d' User entered 'No (N)'	System	05 Dec 2020 07:18:51
	System	05 Dec 2020 07:18:51

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-05T02:18:41', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c5270903-1c05-4560-85dc-23410817da2d' User entered 'No (N)'	System	05 Dec 2020 07:18:51

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-05T02:18:49', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c5270903-1c05-4560-85dc-23410817da2d' User entered '05 Dec 2020 02:18:49'	System	05 Dec 2020 07:18:51
	System	05 Dec 2020 07:18:51

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-12T03:25:04', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ecf2777f-5183-4b65-8654-22a185f427e8'	System	12 Dec 2020 08:26:16
User entered 'Yes (Y)'	System	12 Dec 2020 08:26:16

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-12T03:25:10', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ecf2777f-5183-4b65-8654-22a185f427e8' User entered 'No (N)'	System	12 Dec 2020 08:26:16
	System	12 Dec 2020 08:26:16

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-12T03:25:19', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ecf2777f-5183-4b65-8654-22a185f427e8' User entered 'No (N)'	System	12 Dec 2020 08:26:16
	System	12 Dec 2020 08:26:16

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-12T03:25:27', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ecf2777f-5183-4b65-8654-22a185f427e8'	System	12 Dec 2020 08:26:16
User entered 'Yes (Y)'	System	12 Dec 2020 08:26:16

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Please 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-12T03:25:40', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ecf2777f-5183-4b65-8654-22a185f427e8'	System	12 Dec 2020 08:26:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Dec 2020 08:26:16

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-12T03:26:07', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'ecf2777f-5183-4b65-8654-22a185f427e8' User entered '12 Dec 2020 03:26:07'	System	12 Dec 2020 08:26:16
	System	12 Dec 2020 08:26:16

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-20T17:56:32', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '19be9ed3-f6b7-4837-a5e7-1feff6c7e80d' User entered 'No (N)'	System	20 Dec 2020 22:56:45
	System	20 Dec 2020 22:56:45

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-20T17:56:36', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '19be9ed3-f6b7-4837-a5e7-1feff6c7e80d' User entered 'No (N)'	System	20 Dec 2020 22:56:45
	System	20 Dec 2020 22:56:45

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-20T17:56:40', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '19be9ed3-f6b7-4837-a5e7-1feff6c7e80d' User entered '20 Dec 2020 17:56:40'	System	20 Dec 2020 22:56:45
	System	20 Dec 2020 22:56:45

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-26T01:11:15', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'bef60a5c-3b6b-47b6-ba3e-f5a6de361eb3'	System	26 Dec 2020 06:11:42
User entered 'No (N)'	System	26 Dec 2020 06:11:42

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-26T01:11:19', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'bef60a5c-3b6b-47b6-ba3e-f5a6de361eb3'	System	26 Dec 2020 06:11:42
User entered 'No (N)'	System	26 Dec 2020 06:11:42

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2020-12-26T01:11:40', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'bef60a5c-3b6b-47b6-ba3e-f5a6de361eb3' User entered '26 Dec 2020 01:11:40'	System	26 Dec 2020 06:11:42
	System	26 Dec 2020 06:11:42

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-02T11:07:28', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b63cc7e8-bbd7-4823-b2c8-a960c4793e69' User entered 'No (N)'	System	02 Jan 2021 16:07:43
	System	02 Jan 2021 16:07:43

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-02T11:07:32', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b63cc7e8-bbd7-4823-b2c8-a960c4793e69' User entered 'No (N)'	System	02 Jan 2021 16:07:43

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-02T11:07:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b63cc7e8-bbd7-4823-b2c8-a960c4793e69' User entered '02 Jan 2021 11:07:37'	System	02 Jan 2021 16:07:43
	System	02 Jan 2021 16:07:43

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-09T16:54:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'dda8f365-f08e-40be-9f9c-2fecf391f6c9' User entered 'No (N)'	System	09 Jan 2021 21:54:15

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-09T16:54:04', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'dda8f365-f08e-40be-9f9c-2fecf391f6c9'	System	09 Jan 2021 21:54:15
User entered 'No (N)'	System	09 Jan 2021 21:54:15

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-09T16:54:13', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'dda8f365-f08e-40be-9f9c-2fecf391f6c9' User entered '09 Jan 2021 16:54:13'	System	09 Jan 2021 21:54:15
	System	09 Jan 2021 21:54:15

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-16T18:48:04', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b915585e-e634-4955-aa04-01fa9172fd15'	System	16 Jan 2021 23:48:13
User entered 'No (N)'	System	16 Jan 2021 23:48:13

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-16T18:48:08', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b915585e-e634-4955-aa04-01fa9172fd15'	System	16 Jan 2021 23:48:13
User entered 'No (N)'	System	16 Jan 2021 23:48:13

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-16T18:48:10', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b915585e-e634-4955-aa04-01fa9172fd15' User entered '16 Jan 2021 18:48:10'	System	16 Jan 2021 23:48:13
	System	16 Jan 2021 23:48:13

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-23T10:52:36', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'fbfae9f5-8ce2-4e9a-bb61-0f41a2b8214c' User entered 'No (N)'	System	23 Jan 2021 15:52:49
	System	23 Jan 2021 15:52:49

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-23T10:52:40', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'fbfae9f5-8ce2-4e9a-bb61-0f41a2b8214c' User entered 'No (N)'	System	23 Jan 2021 15:52:49

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-01-23T10:52:45', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'fbfae9f5-8ce2-4e9a-bb61-0f41a2b8214c' User entered '23 Jan 2021 10:52:45'	System	23 Jan 2021 15:52:49

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-01T09:00:04', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e4b45692-37a9-478d-bcac-af8e4ec70d21' User entered 'No (N)'	System	01 Feb 2021 14:00:20
	System	01 Feb 2021 14:00:20

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-01T09:00:11', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e4b45692-37a9-478d-bcac-af8e4ec70d21'	System	01 Feb 2021 14:00:20
User entered 'No (N)'	System	01 Feb 2021 14:00:20

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-01T09:00:18', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e4b45692-37a9-478d-bcac-af8e4ec70d21'	System	01 Feb 2021 14:00:20
User entered '01 Feb 2021 09:00:18'	System	01 Feb 2021 14:00:20

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-07T08:05:59', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c1ac3df9-d5b9-440f-bc5c-bb07453196d5' User entered 'No (N)'	System	07 Feb 2021 13:06:09
	System	07 Feb 2021 13:06:09

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-07T08:06:02', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c1ac3df9-d5b9-440f-bc5c-bb07453196d5' User entered 'No (N)'	System	07 Feb 2021 13:06:09
	System	07 Feb 2021 13:06:09

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-07T08:06:05', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c1ac3df9-d5b9-440f-bc5c-bb07453196d5' User entered '07 Feb 2021 08:06:05'	System	07 Feb 2021 13:06:09
	System	07 Feb 2021 13:06:09

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-13T10:47:35', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e6298461-4e32-47ed-bff2-3ec0eb22e3d9' User entered 'No (N)'	System	13 Feb 2021 15:47:45
	System	13 Feb 2021 15:47:45

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-13T10:47:37', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e6298461-4e32-47ed-bff2-3ec0eb22e3d9' User entered 'No (N)'	System	13 Feb 2021 15:47:45
	System	13 Feb 2021 15:47:45

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-13T10:47:40', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e6298461-4e32-47ed-bff2-3ec0eb22e3d9' User entered '13 Feb 2021 10:47:40'	System	13 Feb 2021 15:47:45
	System	13 Feb 2021 15:47:45

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-21T09:03:55', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '404c22df-fbf5-408b-9a31-c0c267f8ee35' User entered 'No (N)'	System	21 Feb 2021 14:04:05
	System	21 Feb 2021 14:04:05

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-21T09:03:58', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '404c22df-fbf5-408b-9a31-c0c267f8ee35'	System	21 Feb 2021 14:04:05
User entered 'No (N)'	System	21 Feb 2021 14:04:05

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-02-21T09:04:01', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '404c22df-fbf5-408b-9a31-c0c267f8ee35'	System	21 Feb 2021 14:04:05
User entered '21 Feb 2021 09:04:01'	System	21 Feb 2021 14:04:05

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-03T19:41:40-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e8096e05-2170-4e36-8199-774c8822d322'	System	04 Mar 2021 00:42:11
User entered 'No (N)'	System	04 Mar 2021 00:42:11

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-03T19:41:51-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e8096e05-2170-4e36-8199-774c8822d322'	System	04 Mar 2021 00:42:11
User entered 'No (N)'	System	04 Mar 2021 00:42:11

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-03T19:42:06-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'e8096e05-2170-4e36-8199-774c8822d322'	System	04 Mar 2021 00:42:11
User entered '03 Mar 2021 19:42:06'	System	04 Mar 2021 00:42:11

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-06T17:57:29-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7e2a47c7-01d2-47d0-8ddc-f675bb214e0b' User entered 'No (N)'	System	06 Mar 2021 22:57:50
	System	06 Mar 2021 22:57:50

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-06T17:57:35-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7e2a47c7-01d2-47d0-8ddc-f675bb214e0b' User entered 'No (N)'	System	06 Mar 2021 22:57:50
	System	06 Mar 2021 22:57:50

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-06T17:57:45-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '7e2a47c7-01d2-47d0-8ddc-f675bb214e0b' User entered '06 Mar 2021 17:57:45'	System	06 Mar 2021 22:57:50
	System	06 Mar 2021 22:57:50

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-13T09:37:33-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '06ce08b4-409a-4e3e-b07f-913559e16056' User entered 'Yes (Y)'	System	15 Mar 2021 19:39:12
	System	15 Mar 2021 19:39:12

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-13T09:37:41-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '06ce08b4-409a-4e3e-b07f-913559e16056'	System	15 Mar 2021 19:39:12
User entered 'No (N)'	System	15 Mar 2021 19:39:12

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-13T09:37:50-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '06ce08b4-409a-4e3e-b07f-913559e16056'	System	15 Mar 2021 19:39:12
User entered 'No (N)'	System	15 Mar 2021 19:39:12

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-13T09:38:03-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '06ce08b4-409a-4e3e-b07f-913559e16056' User entered 'Yes (Y)'	System	15 Mar 2021 19:39:12
	System	15 Mar 2021 19:39:12

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Please 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-15T15:38:48-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '06ce08b4-409a-4e3e-b07f-913559e16056'	System	15 Mar 2021 19:39:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Mar 2021 19:39:12

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-15T15:39:00-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '06ce08b4-409a-4e3e-b07f-913559e16056' User entered '15 Mar 2021 15:39:00'	System	15 Mar 2021 19:39:12
	System	15 Mar 2021 19:39:12

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-24T20:56:36-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '3e983e8d-0291-4d57-a64c-c1629045721b'	System	25 Mar 2021 00:56:54
User entered 'No (N)'	System	25 Mar 2021 00:56:54

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-24T20:56:42-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '3e983e8d-0291-4d57-a64c-c1629045721b'	System	25 Mar 2021 00:56:54
User entered 'No (N)'	System	25 Mar 2021 00:56:54

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-24T20:56:52-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '3e983e8d-0291-4d57-a64c-c1629045721b' User entered '24 Mar 2021 20:56:52'	System	25 Mar 2021 00:56:54

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-27T15:06:59-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b55e9987-3cd9-4caf-8700-8072ae28e783'	System	27 Mar 2021 19:07:32
User entered 'No (N)'	System	27 Mar 2021 19:07:32

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-27T15:07:09-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b55e9987-3cd9-4caf-8700-8072ae28e783'	System	27 Mar 2021 19:07:32
User entered 'No (N)'	System	27 Mar 2021 19:07:32

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-27T15:07:30-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'b55e9987-3cd9-4caf-8700-8072ae28e783' User entered '27 Mar 2021 15:07:30'	System	27 Mar 2021 19:07:32
	System	27 Mar 2021 19:07:32

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-17T09:12:11-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd125865d-f856-4ee7-b524-4a585f14dc04' User entered 'Yes (Y)'	System	17 Apr 2021 13:12:57
	System	17 Apr 2021 13:12:57

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-17T09:12:15-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd125865d-f856-4ee7-b524-4a585f14dc04' User entered 'No (N)'	System	17 Apr 2021 13:12:57

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-17T09:12:18-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd125865d-f856-4ee7-b524-4a585f14dc04' User entered 'No (N)'	System	17 Apr 2021 13:12:57
	System	17 Apr 2021 13:12:57

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-17T09:12:26-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd125865d-f856-4ee7-b524-4a585f14dc04' User entered 'Yes (Y)'	System	17 Apr 2021 13:12:57

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Please 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-17T09:12:36-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd125865d-f856-4ee7-b524-4a585f14dc04'	System	17 Apr 2021 13:12:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Apr 2021 13:12:57

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-17T09:12:47-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'd125865d-f856-4ee7-b524-4a585f14dc04'	System	17 Apr 2021 13:12:57
User entered '17 Apr 2021 09:12:47'	System	17 Apr 2021 13:12:57

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-24T09:47:01-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '484f55e7-cf62-4f25-a670-247e17ca8743' User entered 'Yes (Y)'	System	24 Apr 2021 13:47:50
	System	24 Apr 2021 13:47:50

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-24T09:47:06-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '484f55e7-cf62-4f25-a670-247e17ca8743' User entered 'No (N)'	System	24 Apr 2021 13:47:50
	System	24 Apr 2021 13:47:50

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-24T09:47:09-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '484f55e7-cf62-4f25-a670-247e17ca8743' User entered 'No (N)'	System	24 Apr 2021 13:47:50
	System	24 Apr 2021 13:47:50

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-24T09:47:20-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '484f55e7-cf62-4f25-a670-247e17ca8743' User entered 'Yes (Y)'	System	24 Apr 2021 13:47:50
	System	24 Apr 2021 13:47:50

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Please 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-24T09:47:31-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '484f55e7-cf62-4f25-a670-247e17ca8743'	System	24 Apr 2021 13:47:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Apr 2021 13:47:50

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-04-24T09:47:41-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '484f55e7-cf62-4f25-a670-247e17ca8743'	System	24 Apr 2021 13:47:50
User entered '24 Apr 2021 09:47:41'	System	24 Apr 2021 13:47:50

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-05-02T12:40:53-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c22c4080-b4cd-497b-9c93-46fafa136c2f' User entered 'No (N)'	System	02 May 2021 16:41:14
	System	02 May 2021 16:41:14

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

Have you been exposed to someone with 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 (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-05-02T12:40:56-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c22c4080-b4cd-497b-9c93-46fafa136c2f' User entered 'No (N)'	System	02 May 2021 16:41:14
	System	02 May 2021 16:41:14

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-05-02T12:41:04-04:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: 'c22c4080-b4cd-497b-9c93-46fafa136c2f' User entered '02 May 2021 12:41:04'	System	02 May 2021 16:41:14
	System	02 May 2021 16:41:14

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:08:18

US3742229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:30:51

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:08:18
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:08:18

US3742229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:30:51

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-03T19:42:31-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '6a521b0f-7afb-4a21-ac85-024f8b125e43'	System	04 Mar 2021 00:42:41
User entered 'No (N)'	System	04 Mar 2021 00:42:41

US3742229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:30:51

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:58:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C2A3BD1-66A9-44AF-AA3C-867B42CF4F02)', Time: '2021-03-03T19:42:38-05:00', User OID: 'PatientReportedOutcome (US3742229)', ODM File OID: '6a521b0f-7afb-4a21-ac85-024f8b125e43'	System	04 Mar 2021 00:42:41
User entered '03 Mar 2021 19:42:38'	System	04 Mar 2021 00:42:41

US3742229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Nov 2020 15:35:23

US3742229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '25 Nov 2020'	Sherry McCammon (b) (4)	25 Nov 2020 15:35:23

US3742229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	25 Nov 2020 15:35:23

US3742229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	Sherry McCammon (b) (4)	25 Nov 2020 15:35:23

US3742229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Nov 2020 15:35:27

US3742229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 11:11:43
User entered 'I'	System	25 Nov 2020 15:35:27

US3742229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:28:01

US3742229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:28:01

US3742229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:28:01

US3742229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:28:01

US3742229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:27:44

US3742229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User entered '1'	System	30 Dec 2020 17:27:44

US3742229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	28 Jan 2021 22:04:18

US3742229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '28 Jan 2021'	Sherry McCammon (b) (4)	28 Jan 2021 22:04:18

US3742229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	28 Jan 2021 22:04:18

US3742229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	Sherry McCammon (b) (4)	28 Jan 2021 22:04:18

US3742229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	28 Jan 2021 22:05:15

US3742229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:34:09
User entered 'I'	System	28 Jan 2021 22:05:15

US3742229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:38
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 14:25:49
	(b) (4)	

US3742229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:38
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '26 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 14:25:49
	(b) (4)	

US3742229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:38
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	01 Mar 2021 14:25:49
	(b) (4)	

US3742229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:30:51

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:38
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:25:49
	(b) (4)	

US3742229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:38
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 14:25:57
	(b) (4)	

US3742229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:11:38
User entered 'I'	System	01 Mar 2021 14:25:57

US3742229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:22:35

US3742229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:22:35

US3742229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:22:35

US3742229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 14:22:35

US3742229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:51

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:22:47

US3742229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:30:51

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:22:47

US3742229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:23:18

US3742229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User entered '30 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:23:18

US3742229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User entered '09:53'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:23:18

US3742229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
User entered '30 Mar 2021 09:53'	System	30 Mar 2021 14:23:18

US3742229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:22:58

US3742229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:30:51

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 14:22:58

US3742229

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

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4)	27 Jan 2021 20:44:11
	(b) (4), (b) (6)	

US3742229

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

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '27 Jan 2021'	(b) (4)	27 Jan 2021 20:44:11
	(b) (4), (b) (6)	

US3742229

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

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:44:11

US3742229

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

Form: Visit Date

Generated On: 10 Jun 2021 09:30:51

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 20:44:11

US3742229

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:36:35
User entered '27 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:36:35
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:45:12

US3742229

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:36:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:28:27

US3742229

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4)	27 Jan 2021 20:45:12
	(b) (4), (b) (6)	

US3742229

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:36:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:28:27

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '27 Jan 2021'	(b) (4)	27 Jan 2021 20:45:12
	(b) (4), (b) (6)	

US3742229

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:45:12

US3742229

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:45:12

US3742229

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:45:12

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4)	27 Jan 2021 20:45:12
	(b) (4), (b) (6)	

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User entered empty.	System	27 Jan 2021 20:45:12

US3742229

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

Form: Unblinding

Generated On: 10 Jun 2021 09:30:51

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User entered empty.	System	27 Jan 2021 20:45:12

US3742229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4)	27 Jan 2021 20:44:27
	(b) (4), (b) (6)	

US3742229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '27 Jan 2021'	(b) (4)	27 Jan 2021 20:44:27
	(b) (4), (b) (6)	

US3742229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '10:12'	(b) (4)	27 Jan 2021 20:44:27
	(b) (4), (b) (6)	

US3742229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User entered '27 Jan 2021 10:12'	System	27 Jan 2021 20:44:27

US3742229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:30:51

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:44:44

US3742229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:30:51

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '27 Jan 2021'	(b) (4)	27 Jan 2021 20:44:44
	(b) (4), (b) (6)	

US3742229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:30:51

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '10:16'	(b) (4)	27 Jan 2021 20:44:44
	(b) (4), (b) (6)	

US3742229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:17:10
User entered '27 Jan 2021 10:16'	System	27 Jan 2021 20:44:44

US3742229

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:30:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:34
User closed query 'Per CDA, per sponsor review: Previous CLR query response noted, however 'Headache' is not recorded on AE log line. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, 'Headache' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 17:56:27
Query 'Per CDA, per sponsor review: Previous CLR query response noted, however 'Headache' is not recorded on AE log line. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, 'Headache' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' answered with 'did not exceed 48 hrs' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Apr 2021 21:10:57
Query 'Per CDA, per sponsor review: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, 'Headache' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' canceled (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 19:10:20

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:30:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDA, per sponsor review: Previous CLR query response noted, however 'Headache' is not recorded on AE log line. Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, 'Headache' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 19:10:07
User opened query 'Per CDA, per sponsor review: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary dose 1, 'Headache' lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 19:08:30
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 10:35:30
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 16:12:39

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:30:51

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of HEADACHE persist beyond Day 7 (start date: Day 1; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	05 Feb 2021 14:29:13
	(b) (4), (b) (6) (b) (4), (b) (6)	08 Oct 2020 12:30:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Apocrine and eccrine gland disorders, PT: Hyperhidrosis, LLT: Diaphoresis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	08 Oct 2020 15:14:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 15:14:41
Data point term sent to Coder	System	08 Oct 2020 12:33:15
User entered 'DIAPHORESIS'	(b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '16:00'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User entered '30 Sep 2020 16:00'	System	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'per CDM: please provide best estimate of time, if possible' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:13
Query 'per CDM: please provide best estimate of time, if possible' answered with 'no information provided' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:42:09
User opened query 'per CDM: please provide best estimate of time, if possible' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:25:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 19:25:21
Query 'Data is required. Please provide.' answered with 'not provided' (Site from System).	Sherry McCammon (b) (4) (b) (4)	13 Oct 2020 16:06:42
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 12:32:24
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User entered empty.	System	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 16:06:58
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	13 Oct 2020 16:06:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	08 Oct 2020 12:32:24
	(b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User entered '0'	System	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55
User entered '0'	System	08 Oct 2020 12:32:24

US3742229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:30:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:55

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Tooth fracture, LLT: Tooth fracture - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	14 Dec 2020 20:21:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Dec 2020 20:21:47
Data point term sent to Coder	System	14 Dec 2020 20:21:03
User entered 'BROKEN TOOTH'	Sherry McCammon (b) (4) (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 20:58:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 20:58:15
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:58:15
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:20:32
User entered empty.	Sherry McCammon (b) (4)	14 Dec 2020 20:20:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '06 Dec 2020'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User entered empty.	System	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:31:23
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	14 Dec 2020 20:20:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	30 Dec 2020 17:31:52
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	30 Dec 2020 17:31:52
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Dec 2020 17:31:23
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:31:23
User entered empty.	Sherry McCammon (b) (4)	14 Dec 2020 20:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User entered empty.	System	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 20:58:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 20:58:15
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:58:15
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:20:32
User entered empty.	Sherry McCammon (b) (4)	14 Dec 2020 20:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 20:58:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 20:58:43
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:58:43
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:20:32
User entered empty.	Sherry McCammon (b) (4)	14 Dec 2020 20:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 20:58:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 20:58:15
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 20:58:15
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:20:32
User entered empty.	Sherry McCammon (b) (4)	14 Dec 2020 20:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 20:58:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 20:58:15
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 20:58:15
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 20:20:32
User entered empty.	Sherry McCammon (b) (4)	14 Dec 2020 20:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'I'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is OTHER and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 18:15:56
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is OTHER and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' answered with 'corrected' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:13:56
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is OTHER and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 11:34:40
User entered 'I'	Sherry McCammon (b) (4) (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:31:52
Data Entry Error		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4) (b) (4)	14 Dec 2020 20:20:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:20:32

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User entered '0'	System	21 Dec 2020 20:58:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57
User entered '1'	System	21 Dec 2020 20:58:15

US3742229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:30:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:11:57

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Post procedural infection, LLT: Post procedural infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	30 Dec 2020 19:51:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 19:51:20
Data point term sent to Coder	System	30 Dec 2020 17:34:41
User entered 'POST EXTRACTION DENTAL INFECTION'	(b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User entered empty.	System	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '24 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User entered empty.	System	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Jan 2021 22:27:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 22:27:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Jan 2021 22:27:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Dec 2020 17:33:46
User entered empty.	System	30 Dec 2020 17:33:46
	(b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Jan 2021 22:27:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 22:27:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Jan 2021 22:27:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Dec 2020 17:33:46
User entered empty.	System	30 Dec 2020 17:33:46
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Jan 2021 22:27:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 22:27:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	19 Jan 2021 22:27:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	30 Dec 2020 17:33:46
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	19 Jan 2021 22:27:41
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	30 Dec 2020 17:33:46
User entered '0'	(b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Sherry McCammon (b) (4)	19 Jan 2021 22:27:41
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Jan 2021 22:27:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Jan 2021 22:27:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Sherry McCammon (b) (4)	19 Jan 2021 22:27:41
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Dec 2020 17:33:46
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:19
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User entered '0'	System	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00
User entered 'I'	System	30 Dec 2020 17:33:46

US3742229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:30:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:12:00

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this worsening AE and please note, the baseline MH condition is listed as resolved and there are no other prior entries of Depression that would support this worsening event. Please review if another baseline condition should be recorded or verify if the MH is condition is ongoing and please update accordingly. Otherwise, consider to remove the term worsening.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 04:30:46
Query 'Per DM CLR: Please review this worsening AE and please note, the baseline MH condition is listed as resolved and there are no other prior entries of Depression that would support this worsening event. Please review if another baseline condition should be recorded or verify if the MH is condition is ongoing and please update accordingly. Otherwise, consider to remove the term worsening.' answered with 'The baseline MH condition is not resolved. it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 20:27:09
User opened query 'Per DM CLR: Please review this worsening AE and please note, the baseline MH condition is listed as resolved and there are no other prior entries of Depression that would support this worsening event. Please review if another baseline condition should be recorded or verify if the MH is condition is ongoing and please update accordingly. Otherwise, consider to remove the term worsening.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 18:09:03
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression worsened - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:29:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:29:50
Data point term sent to Coder	System	01 Mar 2021 14:28:48
User entered 'worsening depression'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '1 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:28:25

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:28:25

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:11:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:11:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 17:11:17
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 14:28:25
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:11:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:11:17
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 17:11:17
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 14:28:25
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:11:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:11:17
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 17:11:17
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 14:28:25
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:28:25
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Mar 2021 14:28:25

US3742229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:30:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 14:28:25

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:45:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:45:50
Data point term sent to Coder	System	01 Mar 2021 14:29:49
User entered 'worsening anxiety'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '1 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:29:32

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:29:32

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4) (b) (4)	14 Mar 2021 21:31:58
User entered empty.	Sherry McCammon (b) (4) (b) (4)	01 Mar 2021 14:29:32

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:11:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:11:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 17:11:55
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 14:29:32
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:11:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:11:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 17:11:55
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 14:29:32
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 17:11:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:11:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 17:11:55
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 14:29:32
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

None

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:31:58
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:29:32
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Mar 2021 14:29:32

US3742229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:30:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 14:29:32

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 14:06:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 14:06:43
	(b) (4)	
Data point term sent to Coder	System	17 Mar 2021 14:05:27
User entered 'constipation'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 16:40:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 16:40:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:40:34
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:04:40
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 16:40:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 16:40:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:40:34
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:04:40
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '3 Mar 2021'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 14:04:40

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 14:04:40

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sherry McCammon (b) (4)	17 Mar 2021 14:04:40

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 16:40:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 16:40:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:40:34
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:04:40
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 16:40:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 16:40:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:40:34
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:04:40
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 16:40:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 16:40:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:40:34
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:04:40
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Mar 2021 16:40:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Mar 2021 16:40:34
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 16:40:34
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 14:04:40
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '1'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:04:40
	(b) (4)	

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Mar 2021 16:40:34

US3742229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:30:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Mar 2021 16:40:34

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 16:05:33
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered	(b) (4)	13 Apr 2021 18:53:48
'USA-US127-2021-mRNA-1273-P301000015'	System	13 Apr 2021 18:53:48
User entered 'New'	(b) (4), (b) (6)	13 Apr 2021 18:53:48

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:46:57
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Major depression, LLT: Psychotic depression - version MedDRA\\23.0.	Coder Import (b) (4)	24 Apr 2021 14:32:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Apr 2021 14:32:59
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 19:11:22
Coding entries removed.	(b) (4), (b) (6)	23 Apr 2021 19:11:13
	(b) (4), (b) (6)	
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 19:11:13
	(b) (4), (b) (6)	
User entered 'Severe major depression with psychotic features' reason for change: New Information	(b) (4), (b) (6)	23 Apr 2021 19:11:13
	(b) (4), (b) (6)	
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Acute depression - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 11:30:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 11:30:57
	(b) (4)	
Data point term sent to Coder	System	13 Apr 2021 11:30:09
User entered 'ACUTE DEPRESSION'	(b) (4), (b) (6)	13 Apr 2021 11:30:08
	(b) (4), (b) (6)	

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered '04 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
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).	(b) (4) System	13 Apr 2021 11:30:58
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	13 Apr 2021 11:30:08
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[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)	29 Apr 2021 17:56:20
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 admission date was provided. Participant readmitted so no discharge date provided. ' (Site from System).	(b) (4), (b) (6)	23 Apr 2021 19:08:35
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	23 Apr 2021 19:06:44
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
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)	13 Apr 2021 11:30:58
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	13 Apr 2021 11:30:58
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 11:30:58
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	13 Apr 2021 11:30:08
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
	(b) (4)	
User entered '04 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 11:30:08

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Folder: Adverse Events

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide hospital discharge date, when available. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 17:10:56
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:46:57
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Apr 2021 19:06:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 19:06:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Apr 2021 19:06:14
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 19:06:14
User entered ' Apr 2021' (non-conformant).	(b) (4), (b) (6)	23 Apr 2021 19:06:14
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
	(b) (4)	
User entered '9 Apr 2021'	(b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 11:30:08

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Folder: Adverse Events

Form: Adverse Events (7)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

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Folder: Adverse Events

Form: Adverse Events (7)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

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Folder: Adverse Events

Form: Adverse Events (7)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

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Folder: Adverse Events

Form: Adverse Events (7)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

None

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Apr 2021 13:29:39
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 13:29:39
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Apr 2021 11:30:08
User entered '0'	(b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Outcome](#)

Audit	User	Time (GMT)
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)	03 May 2021 17:11:32
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)	26 Apr 2021 16:05:02
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 'Participant remains in the hospital' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:09:09
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 Apr 2021 13:59:02
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	13 Apr 2021 11:30:08

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Folder: Adverse Events

Form: Adverse Events (7)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention. 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)	03 May 2021 17:11:14
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)	03 May 2021 17:11:07
User closed query 'PV Query: Please consider whether the event is a worsening of depression based on history of depression and the indication for concomitant medication Mirtazapine noted to be worsening of depression with start date of 24 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:05:27
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)	26 Apr 2021 16:05:23
User closed query 'PV Query: Please provide treatment given for the event including medical intervention. 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)	26 Apr 2021 16:05:16
User signature succeeded.	Milagritos Tapia (b) (4)	26 Apr 2021 14:46:57
Query 'PV Query: Please consider whether the event is a worsening of depression based on history of depression and the indication for concomitant medication Mirtazapine noted to be worsening of depression with start date of 24 Feb 2021.' answered with 'While it may appear to be worsening of depression, the severity and psychotic features are new to this participant' (Site from Safety).	Kaitlin Mason (b) (4)	23 Apr 2021 20:36:23

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention. 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 'Waiting for discharge summary once participant has returned home' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:15:13
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 'Not documented in medical records' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:14:10
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 19:05:33

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT US3742229 WAS HOSPITALIZED FOR ACUTE DEPRESSION FROM 04APR2021 THROUGH 09APR2021. STAFF HAD TRIED MULTIPLE TIMES TO CONTACT PARTICIPANT DUE TO A MISSED DIARY WITHOUT SUCCESS. SITE BECAME AWARE OF THE PARTICIPANT'S HOSPITALIZATION ON 12APR2021 WHEN PARTICIPANT'S WIFE LEFT A MESSAGE ON SITE'S VOICE MAIL. SITE CONTACTED PARTICIPANT AT HOME AND PARTICIPANT VERIFIED HOSPITALIZATION AND DATES. UPDATE 1 Medical records received and reviewed. Participant was hospitalized for severe major depression with psychotic features. The participant, who was hospitalized under emergency petition was "hallucinating, delusional and (b) (6) (b) (6)." During the intake participant reported to the ED physician that he feels like he is being watched by the police. Participant has had a complete neurological work up and with no evidence of any deficits. Participant was stabilized and sent home until ECT treatments could begin. Per the participant's wife he underwent over (b) (6) ECT treatments in 2018. ECT treatments were not reported by the participant during review of medical history at study entrance. Participant was home briefly and was subsequently readmitted due continued depression along with psychosis. There was no significant change, participant's wife was unable to manage him at home. He is currently hospitalized and refusing ECT treatments. Site will continue to follow and will seek additional medical records upon participant's discharge from the hospital.' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 19:05:33
User opened query 'PV Query: Please consider whether the event is a worsening of depression based on history of depression and the indication for concomitant medication Mirtazapine noted to be worsening of depression with start date of 24 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 14:00:33

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Folder: Adverse Events

Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 13:59:49
User opened query 'PV Query: Please provide treatment given for the event including medical intervention. 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 13:58:43
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'Participant US3742229 was hospitalized for acute depression from 04Apr2021 through 09Apr2021. Staff had tried multiple times to contact participant due to a missed diary without success. Site became aware of the participant's hospitalization on 12Apr2021 when participant's wife left a message on site's voice mail. Site contacted participant at home and participant verified hospitalization and dates.'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 11:30:08

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 11:30:08

US3742229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:30:51

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 11:30:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:30:51

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:18:00

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Oct 2020 22:23:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:23:57
Data point term sent to Coder	System	08 Oct 2020 12:22:05
User entered 'LIPITOR'	(b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:20:53
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 19:54:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 19:54:38
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 11:34:13
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'CARDIAC PROTECTION'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '10'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 12:21:08

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Oct 2020 19:15:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 19:15:50
Data point term sent to Coder	System	08 Oct 2020 12:23:06
User entered 'PANTOPRAZOLE'	(b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'ACID REFULX'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '40'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 12:22:14

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 16:51:44
Query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' answered with 'per crohns and colitis foundation aminosalicylates are not immunosuppressive' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	04 Nov 2020 13:56:52
User opened query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 17:58:46
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFLAMMATORY AGENTS, ATC: AMINOSALICYLIC ACID AND SIMILAR AGENTS, PRODUCT: MESALAZINE, PRODUCTSYNONYM: PENTASA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 14:34:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 14:34:16
Data point term sent to Coder	System	08 Oct 2020 12:24:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'PENTASA'	(b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 18:21:13
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 19:55:40
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 19:55:30
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 11:34:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'ULCERTIVE COLITIS PROPHYLAXIS'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '250'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 12:23:07

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Oct 2020 20:08:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 20:08:11
Data point term sent to Coder	System	08 Oct 2020 12:25:07
User entered 'FENTANYL'	(b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'SEDATION FOR COLONOSCOPY'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '2'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User entered empty.	System	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User entered empty.	System	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:18
User entered empty.	System	08 Oct 2020 12:24:28

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 07:18:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Oct 2020 07:18:24
Data point term sent to Coder	System	23 Oct 2020 13:49:33
Coding entries removed.	Sherry McCammon (b) (4)	23 Oct 2020 13:49:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 22:28:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 22:28:48
Data point term sent to Coder	System	08 Oct 2020 12:26:08
User entered 'NIDAZOLAN'	(b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'SEDATION FOR COLONOSCOPY'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 13:49:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 13:49:30
User entered '2' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 13:49:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Oct 2020 12:25:27
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 13:49:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 13:49:30
User entered 'mg (mg)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 13:49:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Oct 2020 12:25:27
User entered empty.	System	08 Oct 2020 12:25:27
	(b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 13:49:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 13:49:30
User entered 'once (ONCE)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 13:49:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Oct 2020 12:25:27
User entered empty.	System	08 Oct 2020 12:25:27
	(b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 13:49:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 13:49:30
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 13:49:30
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Oct 2020 12:25:27
User entered empty.	System	08 Oct 2020 12:25:27
	(b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	23 Oct 2020 13:49:30
User entered '29 Sep 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Oct 2020 13:49:30
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 12:25:27
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User entered empty.	System	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User entered empty.	System	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:13
User entered empty.	System	08 Oct 2020 12:25:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 21:51:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 21:51:44
Data point term sent to Coder Coding entries removed.	System Kaitlin Mason (b) (4)	07 Dec 2020 19:57:23 07 Dec 2020 19:56:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 22:16:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 22:16:09
Data point term sent to Coder User entered 'IBUPROFEN'	System (b) (4), (b) (6)	08 Oct 2020 12:27:09 08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:44:03
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 14:43:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN FEVER did not meet the AE reporting criteria.' answered with 'Did not meet AE reporting criteria ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 19:56:58
Query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 19:56:38
User entered 'generalized PAIN FEVER' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 19:56:27

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 11:33:50
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 11:33:42
User entered 'PAIN FEVER'	(b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '200'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '1 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User entered empty.	System	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User entered empty.	System	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:08
User entered empty.	System	08 Oct 2020 12:26:23

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 19:58:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	07 Dec 2020 19:58:54
Data point term sent to Coder Coding entries removed.	System Kaitlin Mason (b) (4)	07 Dec 2020 19:57:23 07 Dec 2020 19:57:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 14:47:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	08 Oct 2020 14:47:39
Data point term sent to Coder User entered 'ADVIL'	System (b) (4), (b) (6)	08 Oct 2020 12:27:09 08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AND FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AND FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 14:44:28
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 14:44:25
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AND FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AND FEVER did not meet the AE reporting criteria.' answered with 'Did not meet AE reporting criteria ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 19:57:34
Query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 19:57:29
User entered 'generalized PAIN AND FEVER' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	07 Dec 2020 19:57:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN AND FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AND FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 11:32:08
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 11:31:54
User entered 'PAIN AND FEVER'	(b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '200'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User entered empty.	System	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User entered empty.	System	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:02
User entered empty.	System	08 Oct 2020 12:27:06

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
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)	23 Oct 2020 13:55:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 13:55:28
Data point term sent to Coder	System	23 Oct 2020 13:54:39
User entered 'influenza vaccine'	Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'influenza prophylaxis'	Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0.5'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mL (mL)'	Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	23 Oct 2020 13:54:18
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'once (ONCE)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '16 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '16 Oct 2020'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User entered empty.	System	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User entered empty.	System	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:23
User entered empty.	System	23 Oct 2020 13:54:18

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Oct 2020 19:47:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 19:47:51
Data point term sent to Coder	System	28 Oct 2020 18:23:48
Data point term sent to Coder	System	28 Oct 2020 15:43:16
User entered 'vitamin D'	Hassan Haji (b) (4) (b) (4)	28 Oct 2020 15:42:56

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered 'GENERAL HEALTH prophylaxis'	Sherry McCammon (b) (4)	28 Oct 2020 18:23:45
reason for change: Data Entry Error	(b) (4)	
User entered 'general health'	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered '100' reason for change: Data Entry Error	Sherry McCammon (b) (4)	25 Nov 2020 15:37:12
	(b) (4)	
User entered '1'	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry	Sherry McCammon (b) (4)	25 Nov 2020 15:37:12
Error	(b) (4)	
User entered 'tablet (TABLET)'	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered 'once daily (QD)'	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered 'Oral (ORAL)'	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered '27 Oct 2020'	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered '0'	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered 'Yes (Y)'	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered empty.	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
	(b) (4)	
User entered 'No (N)'	Hassan Haji (b) (4)	28 Oct 2020 15:42:56
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:42:56

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:42:56

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 15:42:56

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 20:29:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 20:29:47
Data point term sent to Coder	System	14 Dec 2020 20:28:26
User entered 'TYLENOL'	Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'BROKEN TOOTH'	Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '1000'	Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mg (mg)'	Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'other (OTHER)'	Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'EVERY FOUR HOURS'	Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '11 Dec 2020'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:51:29
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:56:24
User entered '11 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:51:29
User entered empty.	Sherry McCammon (b) (4) (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	Sherry McCammon (b) (4)	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User entered empty.	System	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User entered empty.	System	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:36
User entered empty.	System	14 Dec 2020 20:27:26

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Dec 2020 22:11:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 22:11:57
Data point term sent to Coder	System	14 Dec 2020 20:30:41
User entered 'IBUPROPEN'	Sherry McCammon (b) (4) (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'BROKEN TOOTH'	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '600'	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mg (mg)'	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'other (OTHER)'	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'EVERY 6 HOURS'	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User closed query 'Per DM CLR: Con Med start date is the same as the stop date of the corresponding AE and the stop date of this medication does not match with the AE corresponding stop date. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:03:54
Query 'Per DM CLR: Con Med start date is the same as the stop date of the corresponding AE and the stop date of this medication does not match with the AE corresponding stop date. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Not associated with AE as medicine was taken on day of surgery which is associated to concomitant procedure #2. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 15:38:09
User opened query 'Per DM CLR: Con Med start date is the same as the stop date of the corresponding AE and the stop date of this medication does not match with the AE corresponding stop date. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:54:24
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '11 Dec 2020'	(b) (4) Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:57:35
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '24 Dec 2020' reason for change: Data Entry Error	(b) (4)	30 Dec 2020 17:57:35
User entered empty.	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	Sherry McCammon (b) (4)	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User entered empty.	System	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User entered empty.	System	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:41
User entered empty.	System	14 Dec 2020 20:30:10

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Dec 2020 18:05:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Dec 2020 18:05:19
Data point term sent to Coder	System	30 Dec 2020 18:00:12
User entered 'AMOXICILLIN'	(b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User closed query 'Per DM CLR: This Conmed is given for the AE#3 POST EXTRACTION DENTAL INFECTION. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 12:04:45
Query 'Per DM CLR: This Conmed is given for the AE#3 POST EXTRACTION DENTAL INFECTION. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'The AE Reflects that a CM was given both in source document and edc' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:40:13
User opened query 'Per DM CLR: This Conmed is given for the AE#3 POST EXTRACTION DENTAL INFECTION. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:53:53
Query 'Per DM CLR: This Conmed is given for the AE#3 POST EXTRACTION DENTAL INFECTION. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:53:45
User opened query 'Per DM CLR: This Conmed is given for the AE#3 POST EXTRACTION DENTAL INFECTION. It seems that "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Please review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:53:42
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 17:42:34

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
User entered 'POST EXTRACTION DENTAL INFECTION'	(b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '500'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'four times daily (QID)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	30 Dec 2020 17:59:41
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	30 Dec 2020 17:59:32
User entered '24 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User entered '4'	System	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User entered '1'	System	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:35:29
User entered '804 (804)'	System	30 Dec 2020 17:59:32

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Mar 2021 14:37:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 14:37:50
Data point term sent to Coder	System	01 Mar 2021 14:36:57
User entered 'quetiapine'	Sherry McCammon (b) (4) (b) (4)	01 Mar 2021 14:36:45

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'anxiety'	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '50'	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'twice daily (BID)'	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '8 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 14:36:45
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Mar 2021 14:36:45

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:36:45

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 14:36:45

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Mar 2021 07:42:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:42:01
Data point term sent to Coder	System	01 Mar 2021 14:37:57
User entered 'mirtazapine'	Sherry McCammon (b) (4) (b) (4)	01 Mar 2021 14:37:40

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'worsening depression'	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '15'	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '24 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 14:37:40
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:37:40

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Mar 2021 14:37:40

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 14:37:40

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 20:36:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 20:36:49
Data point term sent to Coder	System	17 Mar 2021 14:02:24
User entered 'Ativan'	Sherry McCammon (b) (4) (b) (4)	17 Mar 2021 14:01:58

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'worsening anxiety'	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0.5'	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'twice daily (BID)'	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '3 Mar 2021'	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:28:57
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	17 Mar 2021 14:01:58
	(b) (4)	

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Mar 2021 14:01:58

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Mar 2021 14:01:58

US3742229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:30:51

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Mar 2021 14:01:58

US3742229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:30:51

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:36:34
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:24:16

US3742229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:30:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:16:19

US3742229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:30:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'COLONSCOPY'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:16:19

US3742229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:16:19

US3742229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:30:51

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 12:16:19

US3742229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:30:51

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:56:28

US3742229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:30:51

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered 'ORAL SURGERY'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:56:28

US3742229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:30:51

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4)	22 Feb 2021 16:12:13
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	22 Feb 2021 16:11:52
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Feb 2021 16:11:52
User entered 'Other (OTHER)'	(b) (4), (b) (6)	21 Dec 2020 20:56:28

US3742229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:30:51

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:34:15
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:42:34
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Feb 2021 16:12:13
User entered 'BROKEN TOOTH'	(b) (4), (b) (6)	21 Dec 2020 20:56:28

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'USA-US127-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Yes (Y)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Yes (Y)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Karen'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Kotloff'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered '685 W. Baltimore Street, HSF 480'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Baltimore'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered '21201'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'US'	(b) (4) System	13 Apr 2021 18:54:27

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 16:06:12
User entered '1'	System	13 Apr 2021 18:54:27

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'USA-US127-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Yes (Y)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Yes (Y)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Karen'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Kotloff'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered '685 W. Baltimore Street, HSF 480'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Baltimore'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered '21201'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'US'	(b) (4) System	13 Apr 2021 18:54:27

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 16:06:12
User entered '1'	System	13 Apr 2021 18:54:27

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:30:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered '13/Apr/2021 14:54'	(b) (4) System	13 Apr 2021 18:54:27

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:30:51

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:27

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'USA-US127-2021-MRNA-1273-P301000015'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Yes (Y)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Yes (Y)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'No (N)'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Karen'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Kotloff'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered '685 W. Baltimore Street, HSF 480'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered 'Baltimore'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:54:16
User entered '21201'	System	13 Apr 2021 18:53:48

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:43:08
User entered 'US'	(b) (4) System	13 Apr 2021 18:54:27

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form

Generated On: 10 Jun 2021 09:30:51

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 16:06:12
User entered '1'	System	13 Apr 2021 18:54:27

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:30:51

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	28 Apr 2021 10:11:06
User entered '26/Apr/2021 12:06'	(b) (4) System	26 Apr 2021 16:06:12

US3742229

Folder: SAE USA-US127-2021-MRNA-1273-P301000015

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:30:51

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	28 Apr 2021 10:11:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:06:12