

US3752129 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:44:11

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US3752129

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 18:30:40

Generated On: 10 Jun 2021 09:44:11

[Participant ID](#)

US3752129

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

US3752129

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	46
Age Units	YEARS
Age (Derived)	46
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 18:30:41

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 18:30:41

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

Condition	THYROID CARCINOMA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

Condition	
Start date (dd MMM yyyy)	
Start date completely unknown	
Condition ongoing at study entry	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	18 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:15 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 10:15
Height (<i>xxx.x</i>)	067.5 in
Weight (<i>xxx.x</i>)	175.0 lb
BMI (<i>xxx.x</i>)	27.06078 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) 12 Feb 2021 18:30:41

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 18:30:41

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Date of assessment (dd MMM yyyy) 18 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 18 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 18:30:41

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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

HUSBAND IS A PHYSICIAN
WHO SEES PATIENTS

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) 12 Feb 2021 18:30:41

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:30:42

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

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

What was the participant's randomization number? 105291

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) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

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) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 10:15
Temperature (xxx.x)	097.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	052 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	070 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 11:50
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

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: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:15 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 11:15

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) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 AUG 2020
Collection time (00:00-23:59)	10:50 (24 HR)
Collection date and time (derived)	18 AUG 2020 10:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:46	18 AUG 2020 10:46
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

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 09:44:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 11:44

PC Open Date & Time

18 AUG 2020 11:35

PC Close Date & Time

18 AUG 2020 14:05

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

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

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

PC Time Stamp 18 AUG 2020 17:55

PC Open Date & Time 18 AUG 2020 15:00

PC Close Date & Time 19 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 20:23

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

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

97.3 °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

20 AUG 2020 18:03

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 16:27

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

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

97.7 °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

22 AUG 2020 15:38

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

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

97.7 °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

23 AUG 2020 12:27

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 13:56

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 11:45

PC Open Date & Time

18 AUG 2020 11:35

PC Close Date & Time

18 AUG 2020 14:05

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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

18 AUG 2020 17:56

PC Open Date & Time

18 AUG 2020 15:00

PC Close Date & Time

19 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 20:23

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 18:03

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

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

21 AUG 2020 16:27

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 15:39

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 12:28

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 13:56

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 11:45
PC Open Date & Time	18 AUG 2020 11:35
PC Close Date & Time	18 AUG 2020 14:05

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 17:56
PC Open Date & Time	18 AUG 2020 15:00
PC Close Date & Time	19 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 20:24
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 18:04
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 16:28
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 15:39
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:28
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 13:56
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3752129

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752129

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752129

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 13:07:26

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

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)	21 SEP 2020
Time of assessment (00:00-23:59)	08:20 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 08:20
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

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)	21 SEP 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:05
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3752129

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	21 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 08:51 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 08:51

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

US3752129

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

08:40 (24 HR)

Collection date and time (derived)

21 SEP 2020 08:40

US3752129

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:38	21 SEP 2020 08:38
Nasopharyngeal Swab 2	No		

US3752129

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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

21 SEP 2020 09:23

PC Open Date & Time

21 SEP 2020 09:11

PC Close Date & Time

21 SEP 2020 11:41

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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 97.9 °F

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

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

PC Time Stamp	21 SEP 2020 17:05
PC Open Date & Time	21 SEP 2020 12:36
PC Close Date & Time	22 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

22 SEP 2020 12:01

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 12:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

24 SEP 2020 12:39

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

25 SEP 2020 14:19

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:13

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

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

97.6 °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

27 SEP 2020 12:11

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 09:23

PC Open Date & Time

21 SEP 2020 09:11

PC Close Date & Time

21 SEP 2020 11:41

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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

21 SEP 2020 17:05

PC Open Date & Time

21 SEP 2020 12:36

PC Close Date & Time

22 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

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

22 SEP 2020 12:01

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

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

23 SEP 2020 12:03

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

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

24 SEP 2020 12:39

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

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

25 SEP 2020 14:19

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

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

26 SEP 2020 12:13

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

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

27 SEP 2020 12:11

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 09:24
PC Open Date & Time	21 SEP 2020 09:11
PC Close Date & Time	21 SEP 2020 11:41

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 17:05
PC Open Date & Time	21 SEP 2020 12:36
PC Close Date & Time	22 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:01
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:03
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 12:39
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 14:19
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 12:13
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

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 ☒

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 12:11
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 28 SEP 2020 12:02

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp 29 SEP 2020 12:00

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:44:11

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	28 SEP 2020 12:02
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:44:11

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	29 SEP 2020 12:00
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3752129

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 13:07:26

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752129

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752129

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	08:28 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 08:28
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752129

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3752129

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 OCT 2020
Collection time (00:00-23:59)	08:29 (24 HR)
Collection date and time (derived)	26 OCT 2020 08:29

US3752129

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:42

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	18 OCT 2020 15:30:36
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 <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	26 OCT 2020 09:21:31
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 NOV 2020 16:32:35

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 103

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 <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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 131

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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Patient Cloud Open Date & Time	24 DEC 2020 00:01
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Patient Cloud Close Date & Time	28 DEC 2020 23:59
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US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

04 JAN 2021 10:08:00

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

09 JAN 2021 12:00:48

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 11:59:16

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 06:28:07

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 11:47:51

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

06 FEB 2021 13:39:19

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 12:00:23

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

21 FEB 2021 17:59:18

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 18:04:50

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 15:29:03

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 22:46:14

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 08:16:57

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 17:59:26

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 11:03:03

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 18:23:10

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 12:02:48

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 12:00:38

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 06:17:56

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 264

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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="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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Patient Cloud Open Date & Time	19 AUG 2021 00:01
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Patient Cloud Close Date & Time	23 AUG 2021 23:59
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US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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="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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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="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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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="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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Patient Cloud Open Date & Time	23 DEC 2021 00:01
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Patient Cloud Close Date & Time	27 DEC 2021 23:59
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US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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="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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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°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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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="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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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="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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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="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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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°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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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"/>

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Date and time of submission

Patient Cloud Open Date & Time	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3752129

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:44:11

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
Yes	No	27 FEB 2021 18:05:09

US3752129

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3752129

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752129

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 18:30:41

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 00:26:55

Generated On: 10 Jun 2021 09:44:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3752129

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 00:26:55

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 17 Mar 2021 20:26:15

Generated On: 10 Jun 2021 09:44:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:14:51

Generated On: 10 Jun 2021 09:44:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 MAR 2021
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	16 MAR 2021 08:05
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752129

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Mar 2021 20:26:15

Generated On: 10 Jun 2021 09:44:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 MAR 2021

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

US3752129

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Mar 2021 20:26:15

Generated On: 10 Jun 2021 09:44:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	08:14 (24 HR)
Collection date and time (derived)	16 MAR 2021 08:14

US3752129

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 17 Mar 2021 20:26:14

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 21 Apr 2021 00:13:01

Generated On: 10 Jun 2021 09:44:11

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3752129

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 21 Apr 2021 00:13:01

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752129

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:44:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3752129

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

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 18:30:40

Generated On: 10 Jun 2021 09:44:11

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

Visit date (dd MMM yyyy)	18 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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US3752129

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

Form: Unblinding

Data signed: (b) (4) 12 Mar 2021 16:17:13

Generated On: 10 Jun 2021 09:44:11

Date of updated informed consent (dd MMM yyyy) 18 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) 18 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 _____

US3752129

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 18:30:40

Generated On: 10 Jun 2021 09:44:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

16:05 (24 HR)

Collection date and time (derived)

18 JAN 2021 16:05

US3752129

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 18:30:40

Generated On: 10 Jun 2021 09:44:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	18 JAN 2021
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Collection time (00:00 - 23:59)	16:01
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Collection Date and Time (derived)	18 JAN 2021 16:01
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US3752129

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 18:30:40

Generated On: 10 Jun 2021 09:44:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Mar 2021 20:26:14

Generated On: 10 Jun 2021 09:44:11

AEID

Adverse event

PAIN AT INJECTION SITE

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)

21 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 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

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EAB) (1725)

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 17 Mar 2021 20:26:14

Generated On: 10 Jun 2021 09:44:11

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 17 Mar 2021 20:26:14

Generated On: 10 Jun 2021 09:44:11

AEID	USA-US113-2020-MRNA-1273-P30 1000010
Adverse event	PAPILLARY THYROID CARCINOMA EXACERBATION
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)	01 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	03 OCT 2020
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 (3)

Data signed: (b) (4) 17 Mar 2021 20:26:14

Generated On: 10 Jun 2021 09:44:11

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	False
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	SUBJECT HAD LEFT THYROID FINE NEEDLE ASPIRATION AND BIOPSY WHICH WAS MALIGNANT, RESULTING IN TOTAL THYROIDECTOMY 02OCT2020.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 17 Mar 2021 20:26:14

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 17 Mar 2021 20:26:14

Generated On: 10 Jun 2021 09:44:11

AEID	
Adverse event	HYPOCALCEMIA
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)	02 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 17 Mar 2021 20:26:14

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 17 Mar 2021 20:26:14

Generated On: 10 Jun 2021 09:44:11

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

US3752129

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 17 Mar 2021 20:26:14

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 06 Mar 2021 00:26:55

Generated On: 10 Jun 2021 09:44:11

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

Yes ☒

No ☐

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

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

Name of Medication MIRENA IUD

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTIVE

Dose per administration 1

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

If dose unit is Other, specify DEVICE

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)

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

	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 checked="" type="radio"/>
If route of administration is Other, specify	UTERINE VIA VAGINA	
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	UN UNK 2019	
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"/>

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

Name of Medication LEVOXYL

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM DUE TO
THYROID CANCER

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 ☐

PRODUCTION RELEASE (v12.003
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US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

	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)		26 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"/>

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☒
No ☐

Indication POST PROCEDURE INFECTION
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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

	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)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

Name of Medication CALCIUM CARBONATE WITH
VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication HYPOCALCEMIA

Dose per administration 500/600

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

If dose unit is Other, specify MG/IU

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 (5)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

	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)		02 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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 440

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

	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)		22 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) 22 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

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 (7)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

	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)		21 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)		21 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"/>

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

Name of Medication TETANUS BOOSTER

Prophylaxis Yes ☒
No ☐

Indication TETANUS 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) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

	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)		15 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 MAR 2021
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"/>

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC ELECTIVE

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Mar 2021 18:36:30

Generated On: 10 Jun 2021 09:44:11

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 FEB 2021		
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"/>

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 18:30:40

Generated On: 10 Jun 2021 09:44:11

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Feb 2021 18:30:40

Generated On: 10 Jun 2021 09:44:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 AUG 2020	LEFT THYROID FINE NEEDLE ASPIRATION WITH BIOPSY	Medical History	
02 OCT 2020	TOTAL THYROIDECTOMY	Adverse Event	
22 OCT 2020	THYROID CANCER ABLATION WITH I-131	Adverse Event	
04 NOV 2020	TOTAL BODY IODINE SCAN	Adverse Event	

US3752129

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:44:11

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

US3752129

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:44:11

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 ☐

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 12 Mar 2021 16:17:13

Generated On: 10 Jun 2021 09:44:11

SAEID	USA-US113-2020-MRNA-1273-P301000010
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Mar 2021 16:17:13

Generated On: 10 Jun 2021 09:44:11

SAEID	USA-US113-2020-MRNA-1273-P301000010
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	10/NOV/2020 15:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Mar 2021 16:17:13

Generated On: 10 Jun 2021 09:44:11

SAEID	USA-US113-2020-MRNA-1273-P301000010
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/NOV/2020 18:22
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

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Mar 2021 16:17:13

Generated On: 10 Jun 2021 09:44:11

SAEID	USA-US113-2020-MRNA-1273-P301000010
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/NOV/2020 20:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Mar 2021 16:17:13

Generated On: 10 Jun 2021 09:44:11

SAEID	USA-US113-2020-MRNA-1273-P301000010
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/DEC/2020 10:18
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

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Mar 2021 16:17:13

Generated On: 10 Jun 2021 09:44:11

SAEID	USA-US113-2020-MRNA-1273-P301000010
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/DEC/2020 11:15
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

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Mar 2021 16:17:13

Generated On: 10 Jun 2021 09:44:11

SAEID	USA-US113-2020-MRNA-1273-P301000010
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/JAN/2021 13:58
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

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (7)

Data signed: (b) (4) 12 Mar 2021 16:17:13

Generated On: 10 Jun 2021 09:44:11

SAEID	USA-US113-2020-MRNA-1273-P301000010
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/MAR/2021 10:54
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

Audit

US3752129 (Prod: Baptist Health Center for Clinical Research)

US3752129

Form: Participant Creation

Generated On: 10 Jun 2021 09:44:11

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'US3752129'	RWS_ENDPOINT	18 Aug 2020 15:10:37
	ENDPOINT (b) (4)	

US3752129

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:18:37

US3752129

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 15:10:38

US3752129

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:18:37

US3752129

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered 'SCRN'	System	18 Aug 2020 16:18:37

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered (b) (6) 1974'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 15:10:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '46'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered 'YEARS'	System	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered '46'	System	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered 'Aug 2020'	System	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered '2020'	System	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:11

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 15:10:38

US3752129

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered 'I'	System	18 Aug 2020 16:19:01

US3752129

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:19:01

US3752129

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:44:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:34:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 21:06:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 21:05:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:03:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 13:31:45
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:22:28

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

Condition

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User closed query 'Per MM, please review and update the term to final diagnosis' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:28:51
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Thyroid cancer, LLT: Thyroid carcinoma - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 17:35:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 17:35:49
	(b) (4)	
Data point term sent to Coder	System	17 Nov 2020 17:34:40
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	17 Nov 2020 17:34:40
Query 'Per MM, please review and update the term to final diagnosis' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 17:34:32
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	17 Nov 2020 17:34:23
User closed query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	17 Nov 2020 17:34:23
User entered 'Thyroid carcinoma' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:34:23

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Response to any significant medical conditions on the Medical History Summary form is No, but Condition has been entered. Please update response, or inactivate this log line.' (Site from System).	System	17 Nov 2020 17:33:44
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
Data point term sent to Coder	System	14 Sep 2020 16:16:40
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Sep 2020 16:16:17
User opened query 'Per MM, please review and update the term to final diagnosis' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 23:22:47
Data point term sent to Coder	System	19 Aug 2020 13:33:00
User entered 'Quarter sized fixed, firm unilateral neck nodule on left side'	(b) (4), (b) (6)	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Sep 2020 16:16:17
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Sep 2020 16:16:17
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Sep 2020 16:16:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Sep 2020 16:16:17
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Sep 2020 16:16:17
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Sep 2020 16:16:17
User entered empty.	System	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Sep 2020 16:16:17
User entered empty.	System	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Sep 2020 16:16:17
User entered empty.	System	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:33:44
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	14 Sep 2020 16:16:17
User entered empty.	System	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

[Condition](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 21:48:20
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '10:15'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered '18 Aug 2020 10:15'	System	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '067.5' in	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:23:35
DataPoint set to visible.	System	18 Aug 2020 16:19:01

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '175.0' lb	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:23:35
DataPoint set to visible.	System	18 Aug 2020 16:19:01

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
Amendment Manager: User entered '27.06078'	System	17 Sep 2020 00:11:53
User entered '27.1'	System	19 Aug 2020 13:23:35
DataPoint set to visible.	System	18 Aug 2020 16:19:01

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered 'kg/m2'	System	19 Aug 2020 13:23:35
DataPoint set to visible.	System	18 Aug 2020 16:19:01

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:21:00
User entered '097.7' F	(b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:21:00
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:21:00
User entered '052'	(b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered 'bpm'	System	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:21:00
User entered '15'	(b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered 'breaths/min'	System	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:21:00
User entered '116'	(b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered 'mmHg'	System	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:21:00
User entered '070'	(b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered 'mmHg'	System	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00

US3752129

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:00:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 18:21:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:23:46

US3752129

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:00:13
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 18:21:21
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:23:46

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:11

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:11

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:11

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:11

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:11

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:11

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:11

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered empty.	System	19 Aug 2020 13:24:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Form: Risk of Exposure

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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)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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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)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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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)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

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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)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Husband is a physician who sees patients'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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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)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Resides in a community with ongoing person to person transmission'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:04

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:30

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:30

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[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 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:30

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'VISIT1'	System	19 Aug 2020 13:27:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:04:39

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:11

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 05:16:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:16:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 16:04:39
User entered '105291' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 16:04:39

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '>=18 and <65 years and not at risk (1)'	(b) (4)	18 Aug 2020 16:04:39
	RWS_ENDPOINT	
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:11

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 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:11

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 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:27:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:04:24
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:34:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:16:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
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)	15 Sep 2020 19:17:33
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)	15 Sep 2020 13:53:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 13:53:26
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)	15 Sep 2020 06:16:55
User entered '067.5' in	(b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:53:26
User entered '175.0' lb	(b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
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)	15 Sep 2020 19:17:33
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)	15 Sep 2020 13:53:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 13:53:26
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)	15 Sep 2020 06:16:55
User entered '067.5' in	(b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:53:26
User entered '175.0' lb	(b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '10:15'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '18 Aug 2020 10:15'	System	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '097.7' F	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:46
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 13:29:46
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 13:29:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Aug 2020 13:29:46
User entered '052' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 13:29:46
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'bpm'	System	19 Aug 2020 13:29:46
User entered empty.	System	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 13:29:46
Query 'Data is required. Please provide.' answered by System	System	19 Aug 2020 13:29:46
data change (Site from System).		
User entered '15' reason for change: Data Entry	(b) (4), (b) (6)	19 Aug 2020 13:29:46
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'breaths/min'	System	19 Aug 2020 13:29:46
User entered empty.	System	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 13:29:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Aug 2020 13:29:46
User entered '116' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 13:29:46
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'mmHg'	System	19 Aug 2020 13:29:46
User entered empty.	System	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 13:29:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Aug 2020 13:29:46
User entered '070' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 13:29:46
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'mmHg'	System	19 Aug 2020 13:29:46
User entered empty.	System	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
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)	15 Sep 2020 19:17:33
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)	15 Sep 2020 13:53:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 13:53:26
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)	15 Sep 2020 06:16:55
User entered '067.5' in	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	15 Sep 2020 13:53:26
User entered '175.0' lb	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:16:53
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 13:29:13
User entered '11:50'	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '18 Aug 2020 11:50'	System	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '98.6' F	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 13:30:29
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 13:30:29
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 13:30:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Aug 2020 13:30:29
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 13:30:29
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'bpm'	System	19 Aug 2020 13:30:29
User entered empty.	System	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 13:30:29
Query 'Data is required. Please provide.' answered by System	System	19 Aug 2020 13:30:29
data change (Site from System).		19 Aug 2020 13:30:29
User entered '14' reason for change: Data Entry	(b) (4), (b) (6)	19 Aug 2020 13:30:29
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'breaths/min'	System	19 Aug 2020 13:30:29
User entered empty.	System	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 13:30:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	19 Aug 2020 13:30:29
User entered '124' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 13:30:29
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:29:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'mmHg'	System	19 Aug 2020 13:30:29
User entered empty.	System	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 13:30:29
Query 'Data is required. Please provide.' answered by System	System	19 Aug 2020 13:30:29
data change (Site from System).		19 Aug 2020 13:30:29
User entered '74' reason for change: Data Entry	(b) (4), (b) (6)	19 Aug 2020 13:30:29
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'mmHg'	System	19 Aug 2020 13:30:29
User entered empty.	System	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
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 then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:16:33
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 then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 13:33:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 13:33:49
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 then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 20:20:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:30:47

US3752129

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 13:33:49
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:30:47

US3752129

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Sep 2020 15:12:11
Query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.'	(b) (4), (b) (6)	09 Sep 2020 21:50:06
answered with 'done' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 21:50:01
User opened query 'Per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 01:23:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:50:01
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:50:01
User entered 'Urine (URINE)'	(b) (4), (b) (6)	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Sep 2020 21:50:01
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:32:11
Query 'per CDM: please select yes or no for this field answered with 'done' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:46:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 16:46:50
User opened query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:35:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 21:50:01
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered empty.	System	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

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 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '11:15'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '18 Aug 2020 11:15'	System	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'ONCE'	System	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:33:56

US3752129

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:33:56

US3752129

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '10:50'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:33:56

US3752129

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '18 Aug 2020 10:50'	System	19 Aug 2020 13:33:56

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:44:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '10:46'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '18 Aug 2020 10:46'	System	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered empty.	System	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 13:34:44

US3752129

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '1'	System	19 Aug 2020 13:34:44

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:44:36', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ce4a30c1-afd4-4151-a8f8-20b7622cf72f' User entered 'Yes (Y)'	System	18 Aug 2020 16:44:58
	System	18 Aug 2020 16:44:58

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:44:45', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ce4a30c1-afd4-4151-a8f8-20b7622cf72f' User entered '98.6'	System	18 Aug 2020 16:44:58
	System	18 Aug 2020 16:44:58

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:44:48', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ce4a30c1-afd4-4151-a8f8-20b7622cf72f'	System	18 Aug 2020 16:44:58
User entered 'No (N)'	System	18 Aug 2020 16:44:58

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:44:55', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ce4a30c1-afd4-4151-a8f8-20b7622cf72f' User entered '18 Aug 2020 11:44'	System	18 Aug 2020 16:44:58
	System	18 Aug 2020 16:44:58

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '18 Aug 2020 11:35'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '18 Aug 2020 14:05'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:55:21', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7e016ed3-1b69-43fd-ab24-1186f24b881f' User entered 'Yes (Y)'	System	18 Aug 2020 22:55:50
	System	18 Aug 2020 22:55:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:55:27', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7e016ed3-1b69-43fd-ab24-1186f24b881f' User entered '98.0'	System	18 Aug 2020 22:55:50
	System	18 Aug 2020 22:55:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:55:31', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7e016ed3-1b69-43fd-ab24-1186f24b881f' User entered 'Yes (Y)'	System	18 Aug 2020 22:55:50
	System	18 Aug 2020 22:55:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:55:39', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7e016ed3-1b69-43fd-ab24-1186f24b881f' User entered '0'	System	18 Aug 2020 22:55:50
	System	18 Aug 2020 22:55:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'subject contacted. medication details reported in concomitant med tab and source. ' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 10:05:23
Query 'Per the participant response, medication was taken to prevent 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 'subject contacted. medication details reported in concomitant med tab and source. ' (Site from System).	(b) (4), (b) (6)	23 Aug 2020 02:46:48
User opened query 'Per the participant response, medication was taken to prevent 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).	System	18 Aug 2020 22:55:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:55:39', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7e016ed3-1b69-43fd-ab24-1186f24b881f'	System	18 Aug 2020 22:55:50
User entered '1'	System	18 Aug 2020 22:55:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:55:45', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7e016ed3-1b69-43fd-ab24-1186f24b881f' User entered '18 Aug 2020 17:55'	System	18 Aug 2020 22:55:50
	System	18 Aug 2020 22:55:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '18 Aug 2020 15:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 2'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:23:01', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'aed346db-c84d-49ba-92bc-fa3fc71bb652'	System	20 Aug 2020 01:23:14
User entered 'Yes (Y)'	System	20 Aug 2020 01:23:14

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:23:05', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'aed346db-c84d-49ba-92bc-fa3fc71bb652' User entered '97.0'	System	20 Aug 2020 01:23:14
	System	20 Aug 2020 01:23:14

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:23:08', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'aed346db-c84d-49ba-92bc-fa3fc71bb652'	System	20 Aug 2020 01:23:14
User entered 'No (N)'	System	20 Aug 2020 01:23:14

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:23:11', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'aed346db-c84d-49ba-92bc-fa3fc71bb652'	System	20 Aug 2020 01:23:14
User entered '19 Aug 2020 20:23'	System	20 Aug 2020 01:23:14

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 3'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:02:55', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '178663e6-1181-43ac-8f47-02a452ae5880' User entered 'Yes (Y)'	System	20 Aug 2020 23:03:18
	System	20 Aug 2020 23:03:18

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:05', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '178663e6-1181-43ac-8f47-02a452ae5880' User entered '97.3'	System	20 Aug 2020 23:03:18
	System	20 Aug 2020 23:03:18

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:10', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '178663e6-1181-43ac-8f47-02a452ae5880'	System	20 Aug 2020 23:03:18
User entered 'No (N)'	System	20 Aug 2020 23:03:18

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:13', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '178663e6-1181-43ac-8f47-02a452ae5880' User entered '20 Aug 2020 18:03'	System	20 Aug 2020 23:03:18
	System	20 Aug 2020 23:03:18

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 4'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:22', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'eaa33819-cdad-40b3-bc51-663713e74fb6' User entered 'Yes (Y)'	System	21 Aug 2020 21:27:34
	System	21 Aug 2020 21:27:34

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:26', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'eaa33819-cdad-40b3-bc51-663713e74fb6' User entered '98.0'	System	21 Aug 2020 21:27:34
	System	21 Aug 2020 21:27:34

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:28', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'eaa33819-cdad-40b3-bc51-663713e74fb6' User entered 'No (N)'	System	21 Aug 2020 21:27:34
	System	21 Aug 2020 21:27:34

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:31', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'eaa33819-cdad-40b3-bc51-663713e74fb6' User entered '21 Aug 2020 16:27'	System	21 Aug 2020 21:27:34
	System	21 Aug 2020 21:27:34

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 5'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:38:38', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '82f37028-c55d-4468-8a45-1cc424406cee' User entered 'Yes (Y)'	System	22 Aug 2020 20:38:50
	System	22 Aug 2020 20:38:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:38:42', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '82f37028-c55d-4468-8a45-1cc424406cee' User entered '97.7'	System	22 Aug 2020 20:38:50
	System	22 Aug 2020 20:38:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:38:44', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '82f37028-c55d-4468-8a45-1cc424406cee' User entered 'No (N)'	System	22 Aug 2020 20:38:50
	System	22 Aug 2020 20:38:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:38:47', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '82f37028-c55d-4468-8a45-1cc424406cee' User entered '22 Aug 2020 15:38'	System	22 Aug 2020 20:38:50
	System	22 Aug 2020 20:38:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 6'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:27:36', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '05e58640-af93-422c-81da-47da59874543' User entered 'Yes (Y)'	System	23 Aug 2020 17:27:48
	System	23 Aug 2020 17:27:48

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:27:41', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '05e58640-af93-422c-81da-47da59874543' User entered '97.7'	System	23 Aug 2020 17:27:48
	System	23 Aug 2020 17:27:48

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:27:43', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '05e58640-af93-422c-81da-47da59874543'	System	23 Aug 2020 17:27:48
User entered 'No (N)'	System	23 Aug 2020 17:27:48

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:27:46', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '05e58640-af93-422c-81da-47da59874543'	System	23 Aug 2020 17:27:48
User entered '23 Aug 2020 12:27'	System	23 Aug 2020 17:27:48

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 7'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:02', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8ce8d00b-56af-4ad3-8ec2-c034057192c0' User entered 'Yes (Y)'	System	24 Aug 2020 18:56:13
	System	24 Aug 2020 18:56:13

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:05', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8ce8d00b-56af-4ad3-8ec2-c034057192c0' User entered '98.0'	System	24 Aug 2020 18:56:13
	System	24 Aug 2020 18:56:13

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:07', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8ce8d00b-56af-4ad3-8ec2-c034057192c0'	System	24 Aug 2020 18:56:13
User entered 'No (N)'	System	24 Aug 2020 18:56:13

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:10', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8ce8d00b-56af-4ad3-8ec2-c034057192c0' User entered '24 Aug 2020 13:56'	System	24 Aug 2020 18:56:13
	System	24 Aug 2020 18:56:13

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:04', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ab4f9dcd-4d47-42ac-9336-f9ff1069d906'	System	18 Aug 2020 16:45:24
User entered 'None (1)'	System	18 Aug 2020 16:45:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:10', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ab4f9dcd-4d47-42ac-9336-f9ff1069d906'	System	18 Aug 2020 16:45:24
User entered 'No (N)'	System	18 Aug 2020 16:45:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:12', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ab4f9dcd-4d47-42ac-9336-f9ff1069d906'	System	18 Aug 2020 16:45:24
User entered 'No (N)'	System	18 Aug 2020 16:45:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:18', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ab4f9dcd-4d47-42ac-9336-f9ff1069d906'	System	18 Aug 2020 16:45:24
User entered 'None (1)'	System	18 Aug 2020 16:45:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:22', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ab4f9dcd-4d47-42ac-9336-f9ff1069d906'	System	18 Aug 2020 16:45:24
User entered '18 Aug 2020 11:45'	System	18 Aug 2020 16:45:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '18 Aug 2020 11:35'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '18 Aug 2020 14:05'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:55:52', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3829948c-132f-40e3-99f9-dab15a10c135'	System	18 Aug 2020 22:56:38
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 22:56:38

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:07', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3829948c-132f-40e3-99f9-dab15a10c135'	System	18 Aug 2020 22:56:38
User entered 'No (N)'	System	18 Aug 2020 22:56:38

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:22', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3829948c-132f-40e3-99f9-dab15a10c135'	System	18 Aug 2020 22:56:38
User entered 'No (N)'	System	18 Aug 2020 22:56:38

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:31', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3829948c-132f-40e3-99f9-dab15a10c135' User entered 'None (1)'	System	18 Aug 2020 22:56:38
	System	18 Aug 2020 22:56:38

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:35', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3829948c-132f-40e3-99f9-dab15a10c135' User entered '18 Aug 2020 17:56'	System	18 Aug 2020 22:56:38
	System	18 Aug 2020 22:56:38

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '18 Aug 2020 15:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 2'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:23:16', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '4ced0282-0133-49c6-8515-e8a4e2eb5cf4'	System	20 Aug 2020 01:23:57
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 01:23:57

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:23:40', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '4ced0282-0133-49c6-8515-e8a4e2eb5cf4'	System	20 Aug 2020 01:23:57
User entered 'No (N)'	System	20 Aug 2020 01:23:57

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:23:51', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '4ced0282-0133-49c6-8515-e8a4e2eb5cf4' User entered 'No (N)'	System	20 Aug 2020 01:23:57
	System	20 Aug 2020 01:23:57

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:23:53', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '4ced0282-0133-49c6-8515-e8a4e2eb5cf4'	System	20 Aug 2020 01:23:57
User entered 'None (1)'	System	20 Aug 2020 01:23:57

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:23:56', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '4ced0282-0133-49c6-8515-e8a4e2eb5cf4' User entered '19 Aug 2020 20:23'	System	20 Aug 2020 01:23:57
	System	20 Aug 2020 01:23:57

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 3'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:19', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ac352e34-9b16-4de3-b1d2-7e42d0832f89'	System	20 Aug 2020 23:03:41
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 23:03:41

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:22', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ac352e34-9b16-4de3-b1d2-7e42d0832f89'	System	20 Aug 2020 23:03:41
User entered 'No (N)'	System	20 Aug 2020 23:03:41

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:32', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ac352e34-9b16-4de3-b1d2-7e42d0832f89'	System	20 Aug 2020 23:03:41
User entered 'No (N)'	System	20 Aug 2020 23:03:41

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:35', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ac352e34-9b16-4de3-b1d2-7e42d0832f89'	System	20 Aug 2020 23:03:41
User entered 'None (1)'	System	20 Aug 2020 23:03:41

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:38', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'ac352e34-9b16-4de3-b1d2-7e42d0832f89' User entered '20 Aug 2020 18:03'	System	20 Aug 2020 23:03:41
	System	20 Aug 2020 23:03:41

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 4'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:36', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '121ba807-1e4f-4e0a-8ffd-81fa667686a4'	System	21 Aug 2020 21:27:49
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 21:27:49

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:40', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '121ba807-1e4f-4e0a-8ffd-81fa667686a4' User entered 'No (N)'	System	21 Aug 2020 21:27:49
	System	21 Aug 2020 21:27:49

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:42', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '121ba807-1e4f-4e0a-8ffd-81fa667686a4'	System	21 Aug 2020 21:27:49
User entered 'No (N)'	System	21 Aug 2020 21:27:49

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:45', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '121ba807-1e4f-4e0a-8ffd-81fa667686a4' User entered 'None (1)'	System	21 Aug 2020 21:27:49
	System	21 Aug 2020 21:27:49

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:48', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '121ba807-1e4f-4e0a-8ffd-81fa667686a4' User entered '21 Aug 2020 16:27'	System	21 Aug 2020 21:27:49
	System	21 Aug 2020 21:27:49

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 5'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:38:52', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f41c1b2e-b906-40d7-b658-c50bfc604bfc'	System	22 Aug 2020 20:39:11
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 20:39:11

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:38:55', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f41c1b2e-b906-40d7-b658-c50bfc604bfc' User entered 'No (N)'	System	22 Aug 2020 20:39:11
	System	22 Aug 2020 20:39:11

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:38:57', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f41c1b2e-b906-40d7-b658-c50bfc604bfc' User entered 'No (N)'	System	22 Aug 2020 20:39:11
	System	22 Aug 2020 20:39:11

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:39:03', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f41c1b2e-b906-40d7-b658-c50bfc604bfc' User entered 'None (1)'	System	22 Aug 2020 20:39:11
	System	22 Aug 2020 20:39:11

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:39:07', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f41c1b2e-b906-40d7-b658-c50bfc604bfc' User entered '22 Aug 2020 15:39'	System	22 Aug 2020 20:39:11
	System	22 Aug 2020 20:39:11

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 6'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:27:51', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0b02755c-e250-4343-a3a2-27f75fdd3202' User entered 'None (1)'	System	23 Aug 2020 17:28:04
	System	23 Aug 2020 17:28:04

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:27:54', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0b02755c-e250-4343-a3a2-27f75fdd3202' User entered 'No (N)'	System	23 Aug 2020 17:28:04
	System	23 Aug 2020 17:28:04

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:27:56', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0b02755c-e250-4343-a3a2-27f75fdd3202' User entered 'No (N)'	System	23 Aug 2020 17:28:04
	System	23 Aug 2020 17:28:04

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:27:58', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0b02755c-e250-4343-a3a2-27f75fdd3202'	System	23 Aug 2020 17:28:04
User entered 'None (1)'	System	23 Aug 2020 17:28:04

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:28:02', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0b02755c-e250-4343-a3a2-27f75fdd3202' User entered '23 Aug 2020 12:28'	System	23 Aug 2020 17:28:04
	System	23 Aug 2020 17:28:04

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 7'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:13', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '73c6106d-1943-4417-86ea-63f646e80ae7' User entered 'None (1)'	System	24 Aug 2020 18:56:24
	System	24 Aug 2020 18:56:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:15', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '73c6106d-1943-4417-86ea-63f646e80ae7' User entered 'No (N)'	System	24 Aug 2020 18:56:24
	System	24 Aug 2020 18:56:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:16', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '73c6106d-1943-4417-86ea-63f646e80ae7' User entered 'No (N)'	System	24 Aug 2020 18:56:24
	System	24 Aug 2020 18:56:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:18', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '73c6106d-1943-4417-86ea-63f646e80ae7' User entered 'None (1)'	System	24 Aug 2020 18:56:24
	System	24 Aug 2020 18:56:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:21', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '73c6106d-1943-4417-86ea-63f646e80ae7' User entered '24 Aug 2020 13:56'	System	24 Aug 2020 18:56:24
	System	24 Aug 2020 18:56:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:26', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e85000f1-95d1-4070-a7fd-85642a476c66'	System	18 Aug 2020 16:45:51
User entered 'None (0)'	System	18 Aug 2020 16:45:51

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:29', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e85000f1-95d1-4070-a7fd-85642a476c66'	System	18 Aug 2020 16:45:51
User entered 'None (0)'	System	18 Aug 2020 16:45:51

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:31', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e85000f1-95d1-4070-a7fd-85642a476c66'	System	18 Aug 2020 16:45:51
User entered 'None (0)'	System	18 Aug 2020 16:45:51

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:33', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e85000f1-95d1-4070-a7fd-85642a476c66' User entered 'None (0)'	System	18 Aug 2020 16:45:51
	System	18 Aug 2020 16:45:51

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:35', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e85000f1-95d1-4070-a7fd-85642a476c66'	System	18 Aug 2020 16:45:51
User entered 'None (0)'	System	18 Aug 2020 16:45:51

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:36', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e85000f1-95d1-4070-a7fd-85642a476c66'	System	18 Aug 2020 16:45:51
User entered 'None (0)'	System	18 Aug 2020 16:45:51

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:44', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e85000f1-95d1-4070-a7fd-85642a476c66'	System	18 Aug 2020 16:45:51
User entered 'No (N)'	System	18 Aug 2020 16:45:51

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T11:45:48', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e85000f1-95d1-4070-a7fd-85642a476c66' User entered '18 Aug 2020 11:45'	System	18 Aug 2020 16:45:51
	System	18 Aug 2020 16:45:51

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '18 Aug 2020 11:35'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '18 Aug 2020 14:05'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:39', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a0f2fd67-a2e6-404b-971e-39d72ec1fe22'	System	18 Aug 2020 22:56:56
User entered 'None (0)'	System	18 Aug 2020 22:56:56

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:41', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a0f2fd67-a2e6-404b-971e-39d72ec1fe22'	System	18 Aug 2020 22:56:56
User entered 'None (0)'	System	18 Aug 2020 22:56:56

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:43', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a0f2fd67-a2e6-404b-971e-39d72ec1fe22'	System	18 Aug 2020 22:56:56
User entered 'None (0)'	System	18 Aug 2020 22:56:56

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:45', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a0f2fd67-a2e6-404b-971e-39d72ec1fe22'	System	18 Aug 2020 22:56:56
User entered 'None (0)'	System	18 Aug 2020 22:56:56

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:46', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a0f2fd67-a2e6-404b-971e-39d72ec1fe22'	System	18 Aug 2020 22:56:56
User entered 'None (0)'	System	18 Aug 2020 22:56:56

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:48', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a0f2fd67-a2e6-404b-971e-39d72ec1fe22'	System	18 Aug 2020 22:56:56
User entered 'None (0)'	System	18 Aug 2020 22:56:56

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:50', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a0f2fd67-a2e6-404b-971e-39d72ec1fe22'	System	18 Aug 2020 22:56:56
User entered 'No (N)'	System	18 Aug 2020 22:56:56

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-18T17:56:54', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a0f2fd67-a2e6-404b-971e-39d72ec1fe22'	System	18 Aug 2020 22:56:56
User entered '18 Aug 2020 17:56'	System	18 Aug 2020 22:56:56

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '18 Aug 2020 15:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 2'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:23:59', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '56f0a26d-c071-47ae-afe8-8eecf95871a0' User entered 'None (0)'	System	20 Aug 2020 01:24:13
	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:24:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '56f0a26d-c071-47ae-afe8-8eecf95871a0' User entered 'None (0)'	System	20 Aug 2020 01:24:13
	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:24:02', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '56f0a26d-c071-47ae-afe8-8eecf95871a0' User entered 'None (0)'	System	20 Aug 2020 01:24:13
	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:24:04', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '56f0a26d-c071-47ae-afe8-8eecf95871a0' User entered 'None (0)'	System	20 Aug 2020 01:24:13
	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:24:05', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '56f0a26d-c071-47ae-afe8-8eecf95871a0' User entered 'None (0)'	System	20 Aug 2020 01:24:13
	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:24:07', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '56f0a26d-c071-47ae-afe8-8eecf95871a0' User entered 'None (0)'	System	20 Aug 2020 01:24:13
	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:24:09', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '56f0a26d-c071-47ae-afe8-8eecf95871a0' User entered 'No (N)'	System	20 Aug 2020 01:24:13
	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-19T20:24:12', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '56f0a26d-c071-47ae-afe8-8eecf95871a0' User entered '19 Aug 2020 20:24'	System	20 Aug 2020 01:24:13
	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 3'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:42', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'c6e42c5c-dbf5-4452-9ef6-0ac913b3f4a5' User entered 'None (0)'	System	20 Aug 2020 23:04:10
	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:44', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'c6e42c5c-dbf5-4452-9ef6-0ac913b3f4a5' User entered 'None (0)'	System	20 Aug 2020 23:04:10
	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:46', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'c6e42c5c-dbf5-4452-9ef6-0ac913b3f4a5' User entered 'None (0)'	System	20 Aug 2020 23:04:10
	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:03:47', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'c6e42c5c-dbf5-4452-9ef6-0ac913b3f4a5' User entered 'None (0)'	System	20 Aug 2020 23:04:10
	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:04:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'c6e42c5c-dbf5-4452-9ef6-0ac913b3f4a5' User entered 'None (0)'	System	20 Aug 2020 23:04:10
	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:04:03', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'c6e42c5c-dbf5-4452-9ef6-0ac913b3f4a5' User entered 'None (0)'	System	20 Aug 2020 23:04:10
	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:04:05', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'c6e42c5c-dbf5-4452-9ef6-0ac913b3f4a5' User entered 'No (N)'	System	20 Aug 2020 23:04:10
	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-20T18:04:08', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'c6e42c5c-dbf5-4452-9ef6-0ac913b3f4a5' User entered '20 Aug 2020 18:04'	System	20 Aug 2020 23:04:10
	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 4'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:51', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'cc85f823-c797-4107-9e7a-c00879d129e0' User entered 'None (0)'	System	21 Aug 2020 21:28:08
	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:52', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'cc85f823-c797-4107-9e7a-c00879d129e0' User entered 'None (0)'	System	21 Aug 2020 21:28:08
	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:54', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'cc85f823-c797-4107-9e7a-c00879d129e0' User entered 'None (0)'	System	21 Aug 2020 21:28:08
	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:55', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'cc85f823-c797-4107-9e7a-c00879d129e0' User entered 'None (0)'	System	21 Aug 2020 21:28:08
	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:57', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'cc85f823-c797-4107-9e7a-c00879d129e0' User entered 'None (0)'	System	21 Aug 2020 21:28:08
	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:27:58', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'cc85f823-c797-4107-9e7a-c00879d129e0' User entered 'None (0)'	System	21 Aug 2020 21:28:08
	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:28:03', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'cc85f823-c797-4107-9e7a-c00879d129e0' User entered 'No (N)'	System	21 Aug 2020 21:28:08
	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-21T16:28:06', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'cc85f823-c797-4107-9e7a-c00879d129e0' User entered '21 Aug 2020 16:28'	System	21 Aug 2020 21:28:08
	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 5'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:39:10', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3b425698-7487-4773-a020-387e4b216290' User entered 'None (0)'	System	22 Aug 2020 20:39:28
	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:39:12', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3b425698-7487-4773-a020-387e4b216290' User entered 'None (0)'	System	22 Aug 2020 20:39:28
	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:39:14', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3b425698-7487-4773-a020-387e4b216290' User entered 'None (0)'	System	22 Aug 2020 20:39:28
	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:39:15', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3b425698-7487-4773-a020-387e4b216290' User entered 'None (0)'	System	22 Aug 2020 20:39:28
	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:39:17', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3b425698-7487-4773-a020-387e4b216290' User entered 'None (0)'	System	22 Aug 2020 20:39:28
	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:39:19', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3b425698-7487-4773-a020-387e4b216290' User entered 'None (0)'	System	22 Aug 2020 20:39:28
	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:39:24', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3b425698-7487-4773-a020-387e4b216290'	System	22 Aug 2020 20:39:28
User entered 'No (N)'	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-22T15:39:27', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '3b425698-7487-4773-a020-387e4b216290' User entered '22 Aug 2020 15:39'	System	22 Aug 2020 20:39:28
	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 6'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:28:05', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '55565b7e-7702-4070-aa52-f3c932051f54' User entered 'None (0)'	System	23 Aug 2020 17:28:20
	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:28:07', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '55565b7e-7702-4070-aa52-f3c932051f54' User entered 'None (0)'	System	23 Aug 2020 17:28:20
	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:28:09', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '55565b7e-7702-4070-aa52-f3c932051f54' User entered 'None (0)'	System	23 Aug 2020 17:28:20
	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:28:10', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '55565b7e-7702-4070-aa52-f3c932051f54' User entered 'None (0)'	System	23 Aug 2020 17:28:20
	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:28:12', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '55565b7e-7702-4070-aa52-f3c932051f54' User entered 'None (0)'	System	23 Aug 2020 17:28:20
	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:28:14', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '55565b7e-7702-4070-aa52-f3c932051f54' User entered 'None (0)'	System	23 Aug 2020 17:28:20
	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:28:16', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '55565b7e-7702-4070-aa52-f3c932051f54' User entered 'No (N)'	System	23 Aug 2020 17:28:20
	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-23T12:28:19', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '55565b7e-7702-4070-aa52-f3c932051f54' User entered '23 Aug 2020 12:28'	System	23 Aug 2020 17:28:20
	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 7'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:24', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a5c106-3ad8-4a2a-9293-2db0194d6855' User entered 'None (0)'	System	24 Aug 2020 18:56:36
	System	24 Aug 2020 18:56:36

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:25', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a5c106-3ad8-4a2a-9293-2db0194d6855'	System	24 Aug 2020 18:56:36
User entered 'None (0)'	System	24 Aug 2020 18:56:36

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:26', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a5c106-3ad8-4a2a-9293-2db0194d6855'	System	24 Aug 2020 18:56:36
User entered 'None (0)'	System	24 Aug 2020 18:56:36

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:28', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a5c106-3ad8-4a2a-9293-2db0194d6855' User entered 'None (0)'	System	24 Aug 2020 18:56:36
	System	24 Aug 2020 18:56:36

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:29', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a5c106-3ad8-4a2a-9293-2db0194d6855'	System	24 Aug 2020 18:56:36
User entered 'None (0)'	System	24 Aug 2020 18:56:36

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:30', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a5c106-3ad8-4a2a-9293-2db0194d6855' User entered 'None (0)'	System	24 Aug 2020 18:56:36
	System	24 Aug 2020 18:56:36

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:32', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a5c106-3ad8-4a2a-9293-2db0194d6855'	System	24 Aug 2020 18:56:36
User entered 'No (N)'	System	24 Aug 2020 18:56:36

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-08-24T13:56:34', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a5c106-3ad8-4a2a-9293-2db0194d6855'	System	24 Aug 2020 18:56:36
User entered '24 Aug 2020 13:56'	System	24 Aug 2020 18:56:36

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 16:19:23

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:04

US3752129

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	23 Sep 2020 20:08:32
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).		23 Sep 2020 20:08:32
User entered '26 Aug 2020' reason for change: Data Entry Error	Amanda Horn (b) (4)	23 Sep 2020 20:08:32
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
	System	22 Sep 2020 18:27:04
User entered '9 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:27:04

US3752129

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:04

US3752129

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:27:04

US3752129

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:54:21

US3752129

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'I'	System	21 Sep 2020 13:54:21

US3752129

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:25:53

US3752129

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '2 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:25:53

US3752129

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:25:53

US3752129

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:25:53

US3752129

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:54:28

US3752129

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'I'	System	21 Sep 2020 13:54:28

US3752129

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:26
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	15 Mar 2021 21:08:56

US3752129

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:26
User entered empty.	(b) (4)	15 Mar 2021 21:08:56
	Lauren Evans (b) (4)	

US3752129

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:26
User entered empty.	(b) (4)	15 Mar 2021 21:08:56
	Lauren Evans (b) (4)	

US3752129

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:26
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 21:08:56

US3752129

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:54:37

US3752129

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'I'	System	21 Sep 2020 13:54:37

US3752129

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:55:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:55:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[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 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:55:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'VISIT2'	System	21 Sep 2020 13:55:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '08:20'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '21 Sep 2020 08:20'	System	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:05:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 18:05:31
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:05:31
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:05:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 18:05:31
User entered '48' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:05:31
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'bpm'	System	21 Sep 2020 18:05:31
User entered empty.	System	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:05:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 18:05:31
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:05:31
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'breaths/min'	System	21 Sep 2020 18:05:31
User entered empty.	System	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:05:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 18:05:31
User entered '115' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:05:31
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'mmHg'	System	21 Sep 2020 18:05:31
User entered empty.	System	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:05:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 18:05:31
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:05:31
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'mmHg'	System	21 Sep 2020 18:05:31
User entered empty.	System	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 18:06:53
User entered '09:05' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:06:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '21 Sep 2020 09:05'	System	21 Sep 2020 18:06:53
User entered empty.	System	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 18:06:53
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:06:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:06:53
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 18:06:53
User entered '52' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:06:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'bpm'	System	21 Sep 2020 18:06:53
User entered empty.	System	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System	System	21 Sep 2020 18:06:53
data change (Site from System).		
User entered '14' reason for change: Data Entry	(b) (4), (b) (6)	21 Sep 2020 18:06:53
Error		
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'breaths/min'	System	21 Sep 2020 18:06:53
User entered empty.	System	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 18:06:53
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:06:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'mmHg'	System	21 Sep 2020 18:06:53
User entered empty.	System	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Sep 2020 18:06:53
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:06:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:09
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'mmHg'	System	21 Sep 2020 18:06:53
User entered empty.	System	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:07:04

US3752129

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:07:04

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered empty.	System	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

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 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '08:51'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '21 Sep 2020 08:51'	System	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'ONCE'	System	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:08:07

US3752129

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:08:07

US3752129

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '08:40'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:08:07

US3752129

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '21 Sep 2020 08:40'	System	21 Sep 2020 18:08:07

US3752129

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:44:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Sep 2020 18:08:37
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		21 Sep 2020 18:08:37
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 18:08:37
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Sep 2020 18:08:21
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:08:21

US3752129

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 18:08:21

US3752129

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:08:21

US3752129

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '08:38'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:08:21

US3752129

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '21 Sep 2020 08:38'	System	21 Sep 2020 18:08:37
User entered '18 Sep 2020 08:38'	System	21 Sep 2020 18:08:21

US3752129

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 18:08:21

US3752129

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:08:21

US3752129

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:08:21

US3752129

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered empty.	System	21 Sep 2020 18:08:21

US3752129

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:08:43

US3752129

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'I'	System	21 Sep 2020 18:08:43

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:17', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '9283c9d5-ed78-4e13-beec-45efdc5f73d7'	System	21 Sep 2020 14:23:29
User entered 'Yes (Y)'	System	21 Sep 2020 14:23:29

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:21', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '9283c9d5-ed78-4e13-beec-45efdc5f73d7' User entered '98.0'	System	21 Sep 2020 14:23:29
	System	21 Sep 2020 14:23:29

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:23', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '9283c9d5-ed78-4e13-beec-45efdc5f73d7'	System	21 Sep 2020 14:23:29
User entered 'No (N)'	System	21 Sep 2020 14:23:29

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:27', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '9283c9d5-ed78-4e13-beec-45efdc5f73d7' User entered '21 Sep 2020 09:23'	System	21 Sep 2020 14:23:29
	System	21 Sep 2020 14:23:29

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Sep 2020 09:11'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Sep 2020 11:41'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:15', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '845b6409-1689-47bc-8d0a-23991f4a4c54' User entered 'Yes (Y)'	System	21 Sep 2020 22:05:26
	System	21 Sep 2020 22:05:26

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:19', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '845b6409-1689-47bc-8d0a-23991f4a4c54' User entered '97.9'	System	21 Sep 2020 22:05:26
	System	21 Sep 2020 22:05:26

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:21', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '845b6409-1689-47bc-8d0a-23991f4a4c54' User entered 'No (N)'	System	21 Sep 2020 22:05:26
	System	21 Sep 2020 22:05:26

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:23', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '845b6409-1689-47bc-8d0a-23991f4a4c54' User entered '21 Sep 2020 17:05'	System	21 Sep 2020 22:05:26
	System	21 Sep 2020 22:05:26

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Sep 2020 12:36'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 2'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:00:45', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6a931a33-f572-422f-9482-bb0647490273' User entered 'Yes (Y)'	System	22 Sep 2020 17:01:51
	System	22 Sep 2020 17:01:51

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:00:49', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6a931a33-f572-422f-9482-bb0647490273' User entered '98.0'	System	22 Sep 2020 17:01:51
	System	22 Sep 2020 17:01:51

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:00:52', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6a931a33-f572-422f-9482-bb0647490273'	System	22 Sep 2020 17:01:51
User entered 'Yes (Y)'	System	22 Sep 2020 17:01:51

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
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 'Site confirmed with subject, EDC being updated accordingly.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 22:05:36
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)	23 Sep 2020 14:34:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:00:56', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6a931a33-f572-422f-9482-bb0647490273'	System	22 Sep 2020 17:01:51
User entered '1'	System	22 Sep 2020 17:01:51

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:00:56', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6a931a33-f572-422f-9482-bb0647490273' User entered '0'	System	22 Sep 2020 17:01:51
	System	22 Sep 2020 17:01:51

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:02', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6a931a33-f572-422f-9482-bb0647490273' User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:01:51
	System	22 Sep 2020 17:01:51

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 3'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:02:56', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '263df54b-e1d3-478d-957f-b9876e04df02'	System	23 Sep 2020 17:07:01
User entered 'Yes (Y)'	System	23 Sep 2020 17:07:01

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '263df54b-e1d3-478d-957f-b9876e04df02'	System	23 Sep 2020 17:07:01
User entered '98.3'	System	23 Sep 2020 17:07:01

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:03', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '263df54b-e1d3-478d-957f-b9876e04df02'	System	23 Sep 2020 17:07:01
User entered 'No (N)'	System	23 Sep 2020 17:07:01

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:06', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '263df54b-e1d3-478d-957f-b9876e04df02'	System	23 Sep 2020 17:07:01
User entered '23 Sep 2020 12:03'	System	23 Sep 2020 17:07:01

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 4'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:06', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '97693fe9-5c7a-46b4-bd10-b3e5ed8ad4a5'	System	24 Sep 2020 17:39:17
User entered 'Yes (Y)'	System	24 Sep 2020 17:39:17

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:09', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '97693fe9-5c7a-46b4-bd10-b3e5ed8ad4a5' User entered '98.6'	System	24 Sep 2020 17:39:17
	System	24 Sep 2020 17:39:17

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:11', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '97693fe9-5c7a-46b4-bd10-b3e5ed8ad4a5'	System	24 Sep 2020 17:39:17
User entered 'No (N)'	System	24 Sep 2020 17:39:17

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:14', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '97693fe9-5c7a-46b4-bd10-b3e5ed8ad4a5' User entered '24 Sep 2020 12:39'	System	24 Sep 2020 17:39:17
	System	24 Sep 2020 17:39:17

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 5'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:07', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f10d908c-1b3b-42ff-b4e0-1a168111330c' User entered 'Yes (Y)'	System	25 Sep 2020 19:19:19
	System	25 Sep 2020 19:19:19

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:12', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f10d908c-1b3b-42ff-b4e0-1a168111330c' User entered '96.3'	System	25 Sep 2020 19:19:19
	System	25 Sep 2020 19:19:19

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:14', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f10d908c-1b3b-42ff-b4e0-1a168111330c' User entered 'No (N)'	System	25 Sep 2020 19:19:19
	System	25 Sep 2020 19:19:19

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:16', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f10d908c-1b3b-42ff-b4e0-1a168111330c' User entered '25 Sep 2020 14:19'	System	25 Sep 2020 19:19:19
	System	25 Sep 2020 19:19:19

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 6'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:12:51', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8efe95ea-94b9-40db-850c-8c6847bafa51' User entered 'Yes (Y)'	System	26 Sep 2020 17:13:06
	System	26 Sep 2020 17:13:06

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:12:56', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8efe95ea-94b9-40db-850c-8c6847bafa51' User entered '97.6'	System	26 Sep 2020 17:13:06
	System	26 Sep 2020 17:13:06

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:12:58', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8efe95ea-94b9-40db-850c-8c6847bafa51'	System	26 Sep 2020 17:13:06
User entered 'No (N)'	System	26 Sep 2020 17:13:06

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:01', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8efe95ea-94b9-40db-850c-8c6847bafa51' User entered '26 Sep 2020 12:13'	System	26 Sep 2020 17:13:06
	System	26 Sep 2020 17:13:06

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 7'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:09', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e842b804-9e41-4a8e-bd84-c28bbd6e82c8' User entered 'Yes (Y)'	System	27 Sep 2020 17:11:23
	System	27 Sep 2020 17:11:23

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:13', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e842b804-9e41-4a8e-bd84-c28bbd6e82c8' User entered '97.6'	System	27 Sep 2020 17:11:23
	System	27 Sep 2020 17:11:23

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:16', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e842b804-9e41-4a8e-bd84-c28bbd6e82c8' User entered 'No (N)'	System	27 Sep 2020 17:11:23
	System	27 Sep 2020 17:11:23

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:18', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e842b804-9e41-4a8e-bd84-c28bbd6e82c8' User entered '27 Sep 2020 12:11'	System	27 Sep 2020 17:11:23
	System	27 Sep 2020 17:11:23

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:33', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6ea1393c-b742-4135-948e-af146116f4b4' User entered 'None (1)'	System	21 Sep 2020 14:23:47
	System	21 Sep 2020 14:23:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:36', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6ea1393c-b742-4135-948e-af146116f4b4' User entered 'No (N)'	System	21 Sep 2020 14:23:47
	System	21 Sep 2020 14:23:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:38', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6ea1393c-b742-4135-948e-af146116f4b4' User entered 'No (N)'	System	21 Sep 2020 14:23:47
	System	21 Sep 2020 14:23:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:40', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6ea1393c-b742-4135-948e-af146116f4b4' User entered 'None (1)'	System	21 Sep 2020 14:23:47
	System	21 Sep 2020 14:23:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:43', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6ea1393c-b742-4135-948e-af146116f4b4' User entered '21 Sep 2020 09:23'	System	21 Sep 2020 14:23:47
	System	21 Sep 2020 14:23:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Sep 2020 09:11'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Sep 2020 11:41'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:31', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'db246b16-9c2b-41e7-8c1d-2c227e8fc3b2'	System	21 Sep 2020 22:05:41
User entered 'Does not interfere with activity (2)'	System	21 Sep 2020 22:05:41

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:33', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'db246b16-9c2b-41e7-8c1d-2c227e8fc3b2'	System	21 Sep 2020 22:05:41
User entered 'No (N)'	System	21 Sep 2020 22:05:41

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:35', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'db246b16-9c2b-41e7-8c1d-2c227e8fc3b2'	System	21 Sep 2020 22:05:41
User entered 'No (N)'	System	21 Sep 2020 22:05:41

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:36', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'db246b16-9c2b-41e7-8c1d-2c227e8fc3b2'	System	21 Sep 2020 22:05:41
User entered 'None (1)'	System	21 Sep 2020 22:05:41

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:39', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'db246b16-9c2b-41e7-8c1d-2c227e8fc3b2'	System	21 Sep 2020 22:05:41
User entered '21 Sep 2020 17:05'	System	21 Sep 2020 22:05:41

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Sep 2020 12:36'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 2'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:17', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '31072f01-7178-44a5-81bc-e9c97783b900'	System	22 Sep 2020 17:02:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Sep 2020 17:02:30

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:19', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '31072f01-7178-44a5-81bc-e9c97783b900' User entered 'No (N)'	System	22 Sep 2020 17:02:30
	System	22 Sep 2020 17:02:30

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:21', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '31072f01-7178-44a5-81bc-e9c97783b900' User entered 'No (N)'	System	22 Sep 2020 17:02:30
	System	22 Sep 2020 17:02:30

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:25', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '31072f01-7178-44a5-81bc-e9c97783b900'	System	22 Sep 2020 17:02:30
User entered 'None (1)'	System	22 Sep 2020 17:02:30

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:27', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '31072f01-7178-44a5-81bc-e9c97783b900' User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:02:30
	System	22 Sep 2020 17:02:30

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 3'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:11', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd11821a8-09a6-4500-940d-29a84ee59162'	System	23 Sep 2020 17:07:16
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 17:07:16

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:14', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd11821a8-09a6-4500-940d-29a84ee59162' User entered 'No (N)'	System	23 Sep 2020 17:07:16
	System	23 Sep 2020 17:07:16

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:16', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd11821a8-09a6-4500-940d-29a84ee59162' User entered 'No (N)'	System	23 Sep 2020 17:07:16
	System	23 Sep 2020 17:07:16

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:19', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd11821a8-09a6-4500-940d-29a84ee59162'	System	23 Sep 2020 17:07:16
User entered 'None (1)'	System	23 Sep 2020 17:07:16

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:21', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd11821a8-09a6-4500-940d-29a84ee59162' User entered '23 Sep 2020 12:03'	System	23 Sep 2020 17:07:16
	System	23 Sep 2020 17:07:16

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 4'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:19', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'aa69c234-fa53-43ef-b41c-60c1b760fc47'	System	24 Sep 2020 17:39:29
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 17:39:29

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:21', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'aa69c234-fa53-43ef-b41c-60c1b760fc47'	System	24 Sep 2020 17:39:29
User entered 'No (N)'	System	24 Sep 2020 17:39:29

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:23', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'aa69c234-fa53-43ef-b41c-60c1b760fc47'	System	24 Sep 2020 17:39:29
User entered 'No (N)'	System	24 Sep 2020 17:39:29

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:26', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'aa69c234-fa53-43ef-b41c-60c1b760fc47'	System	24 Sep 2020 17:39:29
User entered 'None (1)'	System	24 Sep 2020 17:39:29

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:28', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'aa69c234-fa53-43ef-b41c-60c1b760fc47'	System	24 Sep 2020 17:39:29
User entered '24 Sep 2020 12:39'	System	24 Sep 2020 17:39:29

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 5'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:22', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '537788da-4afd-405e-85f1-a319ec29ea64'	System	25 Sep 2020 19:19:33
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 19:19:33

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:24', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '537788da-4afd-405e-85f1-a319ec29ea64'	System	25 Sep 2020 19:19:33
User entered 'No (N)'	System	25 Sep 2020 19:19:33

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:25', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '537788da-4afd-405e-85f1-a319ec29ea64'	System	25 Sep 2020 19:19:33
User entered 'No (N)'	System	25 Sep 2020 19:19:33

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:27', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '537788da-4afd-405e-85f1-a319ec29ea64'	System	25 Sep 2020 19:19:33
User entered 'None (1)'	System	25 Sep 2020 19:19:33

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:30', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '537788da-4afd-405e-85f1-a319ec29ea64' User entered '25 Sep 2020 14:19'	System	25 Sep 2020 19:19:33
	System	25 Sep 2020 19:19:33

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 6'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:04', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f8e5796f-1a26-4d77-8f13-16edc1c4945a'	System	26 Sep 2020 17:13:13
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:06', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f8e5796f-1a26-4d77-8f13-16edc1c4945a' User entered 'No (N)'	System	26 Sep 2020 17:13:13
	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:07', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f8e5796f-1a26-4d77-8f13-16edc1c4945a' User entered 'No (N)'	System	26 Sep 2020 17:13:13
	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:09', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f8e5796f-1a26-4d77-8f13-16edc1c4945a' User entered 'None (1)'	System	26 Sep 2020 17:13:13
	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:11', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'f8e5796f-1a26-4d77-8f13-16edc1c4945a' User entered '26 Sep 2020 12:13'	System	26 Sep 2020 17:13:13
	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 7'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:23', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0e1eec68-e95f-418a-be5f-7cd76cc9af24'	System	27 Sep 2020 17:11:34
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:25', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0e1eec68-e95f-418a-be5f-7cd76cc9af24' User entered 'No (N)'	System	27 Sep 2020 17:11:34
	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:27', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0e1eec68-e95f-418a-be5f-7cd76cc9af24' User entered 'No (N)'	System	27 Sep 2020 17:11:34
	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:29', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0e1eec68-e95f-418a-be5f-7cd76cc9af24' User entered 'None (1)'	System	27 Sep 2020 17:11:34
	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:31', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0e1eec68-e95f-418a-be5f-7cd76cc9af24' User entered '27 Sep 2020 12:11'	System	27 Sep 2020 17:11:34
	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:46', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7d820f63-44c2-4456-8567-023712536541' User entered 'None (0)'	System	21 Sep 2020 14:25:27
	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:48', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7d820f63-44c2-4456-8567-023712536541' User entered 'None (0)'	System	21 Sep 2020 14:25:27
	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:49', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7d820f63-44c2-4456-8567-023712536541' User entered 'None (0)'	System	21 Sep 2020 14:25:27
	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:51', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7d820f63-44c2-4456-8567-023712536541' User entered 'None (0)'	System	21 Sep 2020 14:25:27
	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:53', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7d820f63-44c2-4456-8567-023712536541' User entered 'None (0)'	System	21 Sep 2020 14:25:27
	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:54', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7d820f63-44c2-4456-8567-023712536541' User entered 'None (0)'	System	21 Sep 2020 14:25:27
	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:23:57', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7d820f63-44c2-4456-8567-023712536541' User entered 'No (N)'	System	21 Sep 2020 14:25:27
	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T09:24:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7d820f63-44c2-4456-8567-023712536541' User entered '21 Sep 2020 09:24'	System	21 Sep 2020 14:25:27
	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Sep 2020 09:11'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Sep 2020 11:41'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:42', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '174e7f56-046c-40e5-8eb1-7655bd6fa1fc' User entered 'None (0)'	System	21 Sep 2020 22:05:55
	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:43', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '174e7f56-046c-40e5-8eb1-7655bd6fa1fc' User entered 'None (0)'	System	21 Sep 2020 22:05:55
	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:44', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '174e7f56-046c-40e5-8eb1-7655bd6fa1fc' User entered 'None (0)'	System	21 Sep 2020 22:05:55
	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:46', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '174e7f56-046c-40e5-8eb1-7655bd6fa1fc' User entered 'None (0)'	System	21 Sep 2020 22:05:55
	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:47', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '174e7f56-046c-40e5-8eb1-7655bd6fa1fc' User entered 'None (0)'	System	21 Sep 2020 22:05:55
	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:49', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '174e7f56-046c-40e5-8eb1-7655bd6fa1fc' User entered 'None (0)'	System	21 Sep 2020 22:05:55
	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:50', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '174e7f56-046c-40e5-8eb1-7655bd6fa1fc' User entered 'No (N)'	System	21 Sep 2020 22:05:55
	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-21T17:05:53', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '174e7f56-046c-40e5-8eb1-7655bd6fa1fc' User entered '21 Sep 2020 17:05'	System	21 Sep 2020 22:05:55
	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '21 Sep 2020 12:36'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 2'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:31', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'bb4211e1-59f8-4a09-a520-378cad5246e5' User entered 'None (0)'	System	22 Sep 2020 17:03:25
	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:32', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'bb4211e1-59f8-4a09-a520-378cad5246e5' User entered 'None (0)'	System	22 Sep 2020 17:03:25
	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:34', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'bb4211e1-59f8-4a09-a520-378cad5246e5' User entered 'None (0)'	System	22 Sep 2020 17:03:25
	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:36', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'bb4211e1-59f8-4a09-a520-378cad5246e5' User entered 'None (0)'	System	22 Sep 2020 17:03:25
	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:38', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'bb4211e1-59f8-4a09-a520-378cad5246e5' User entered 'None (0)'	System	22 Sep 2020 17:03:25
	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:39', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'bb4211e1-59f8-4a09-a520-378cad5246e5' User entered 'None (0)'	System	22 Sep 2020 17:03:25
	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:42', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'bb4211e1-59f8-4a09-a520-378cad5246e5' User entered 'No (N)'	System	22 Sep 2020 17:03:25
	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-22T12:01:44', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'bb4211e1-59f8-4a09-a520-378cad5246e5' User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:03:25
	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 3'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:26', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd9b42099-51b3-402f-9ba3-1343a8282da7' User entered 'None (0)'	System	23 Sep 2020 17:07:32
	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:28', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd9b42099-51b3-402f-9ba3-1343a8282da7' User entered 'None (0)'	System	23 Sep 2020 17:07:32
	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:30', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd9b42099-51b3-402f-9ba3-1343a8282da7' User entered 'None (0)'	System	23 Sep 2020 17:07:32
	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:31', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd9b42099-51b3-402f-9ba3-1343a8282da7' User entered 'None (0)'	System	23 Sep 2020 17:07:32
	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:33', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd9b42099-51b3-402f-9ba3-1343a8282da7' User entered 'None (0)'	System	23 Sep 2020 17:07:32
	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:35', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd9b42099-51b3-402f-9ba3-1343a8282da7' User entered 'None (0)'	System	23 Sep 2020 17:07:32
	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:37', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd9b42099-51b3-402f-9ba3-1343a8282da7'	System	23 Sep 2020 17:07:32
User entered 'No (N)'	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-23T12:03:40', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd9b42099-51b3-402f-9ba3-1343a8282da7' User entered '23 Sep 2020 12:03'	System	23 Sep 2020 17:07:32
	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 4'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:31', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8b021d9e-4b7d-4d17-b5b9-1152f901f67d' User entered 'None (0)'	System	24 Sep 2020 17:39:45
	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:32', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8b021d9e-4b7d-4d17-b5b9-1152f901f67d' User entered 'None (0)'	System	24 Sep 2020 17:39:45
	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:34', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8b021d9e-4b7d-4d17-b5b9-1152f901f67d' User entered 'None (0)'	System	24 Sep 2020 17:39:45
	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:35', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8b021d9e-4b7d-4d17-b5b9-1152f901f67d' User entered 'None (0)'	System	24 Sep 2020 17:39:45
	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:37', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8b021d9e-4b7d-4d17-b5b9-1152f901f67d' User entered 'None (0)'	System	24 Sep 2020 17:39:45
	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:38', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8b021d9e-4b7d-4d17-b5b9-1152f901f67d' User entered 'None (0)'	System	24 Sep 2020 17:39:45
	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:41', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8b021d9e-4b7d-4d17-b5b9-1152f901f67d' User entered 'No (N)'	System	24 Sep 2020 17:39:45
	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-24T12:39:43', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '8b021d9e-4b7d-4d17-b5b9-1152f901f67d' User entered '24 Sep 2020 12:39'	System	24 Sep 2020 17:39:45
	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 5'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:33', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0fbd7ba8-4197-4502-90fc-a2539fb182f0' User entered 'None (0)'	System	25 Sep 2020 19:19:51
	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:35', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0fbd7ba8-4197-4502-90fc-a2539fb182f0' User entered 'None (0)'	System	25 Sep 2020 19:19:51
	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:37', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0fbd7ba8-4197-4502-90fc-a2539fb182f0' User entered 'None (0)'	System	25 Sep 2020 19:19:51
	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:38', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0fbd7ba8-4197-4502-90fc-a2539fb182f0' User entered 'None (0)'	System	25 Sep 2020 19:19:51
	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:42', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0fbd7ba8-4197-4502-90fc-a2539fb182f0' User entered 'None (0)'	System	25 Sep 2020 19:19:51
	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:44', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0fbd7ba8-4197-4502-90fc-a2539fb182f0' User entered 'None (0)'	System	25 Sep 2020 19:19:51
	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:46', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0fbd7ba8-4197-4502-90fc-a2539fb182f0' User entered 'No (N)'	System	25 Sep 2020 19:19:51
	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-25T14:19:49', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '0fbd7ba8-4197-4502-90fc-a2539fb182f0' User entered '25 Sep 2020 14:19'	System	25 Sep 2020 19:19:51
	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 6'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:14', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '29af3baf-a5e5-45c9-9c38-c5e093d1aad0' User entered 'None (0)'	System	26 Sep 2020 17:13:28
	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:15', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '29af3baf-a5e5-45c9-9c38-c5e093d1aad0' User entered 'None (0)'	System	26 Sep 2020 17:13:28
	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:16', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '29af3baf-a5e5-45c9-9c38-c5e093d1aad0' User entered 'None (0)'	System	26 Sep 2020 17:13:28
	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:18', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '29af3baf-a5e5-45c9-9c38-c5e093d1aad0' User entered 'None (0)'	System	26 Sep 2020 17:13:28
	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:19', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '29af3baf-a5e5-45c9-9c38-c5e093d1aad0' User entered 'None (0)'	System	26 Sep 2020 17:13:28
	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:20', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '29af3baf-a5e5-45c9-9c38-c5e093d1aad0' User entered 'None (0)'	System	26 Sep 2020 17:13:28
	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:22', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '29af3baf-a5e5-45c9-9c38-c5e093d1aad0' User entered 'No (N)'	System	26 Sep 2020 17:13:28
	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-26T12:13:24', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '29af3baf-a5e5-45c9-9c38-c5e093d1aad0' User entered '26 Sep 2020 12:13'	System	26 Sep 2020 17:13:28
	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	21 Sep 2020 13:56:09
User entered 'Day 7'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:34', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e3f24bf4-956e-4d71-a642-649f7436ff44' User entered 'None (0)'	System	27 Sep 2020 17:11:50
	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:35', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e3f24bf4-956e-4d71-a642-649f7436ff44' User entered 'None (0)'	System	27 Sep 2020 17:11:50
	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:37', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e3f24bf4-956e-4d71-a642-649f7436ff44' User entered 'None (0)'	System	27 Sep 2020 17:11:50
	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:38', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e3f24bf4-956e-4d71-a642-649f7436ff44' User entered 'None (0)'	System	27 Sep 2020 17:11:50
	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:40', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e3f24bf4-956e-4d71-a642-649f7436ff44' User entered 'None (0)'	System	27 Sep 2020 17:11:50
	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:41', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e3f24bf4-956e-4d71-a642-649f7436ff44' User entered 'None (0)'	System	27 Sep 2020 17:11:50
	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:44', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e3f24bf4-956e-4d71-a642-649f7436ff44'	System	27 Sep 2020 17:11:50
User entered 'No (N)'	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-27T12:11:47', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e3f24bf4-956e-4d71-a642-649f7436ff44' User entered '27 Sep 2020 12:11'	System	27 Sep 2020 17:11:50
	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:56:09

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	26 Sep 2020 17:13:13
User entered 'Day 8'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-28T12:02:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '666b93a5-50bc-41b8-b9bf-260f2d39fae1'	System	28 Sep 2020 17:02:38
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 17:02:38

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-28T12:02:04', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '666b93a5-50bc-41b8-b9bf-260f2d39fae1' User entered '28 Sep 2020 12:02'	System	28 Sep 2020 17:02:38
	System	28 Sep 2020 17:02:38

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	27 Sep 2020 17:11:34
User entered 'Day 9'	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-29T12:00:36', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '198f9fec-10fc-48b0-891d-13f48942cc24'	System	29 Sep 2020 17:00:47
User entered 'None (1)'	System	29 Sep 2020 17:00:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 09:44:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-29T12:00:40', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '198f9fec-10fc-48b0-891d-13f48942cc24' User entered '29 Sep 2020 12:00'	System	29 Sep 2020 17:00:47
	System	29 Sep 2020 17:00:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	26 Sep 2020 17:13:13
User entered 'Day 8'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-28T12:02:08', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'c7725472-1c88-47cf-9fc5-761d1cfe1884' User entered 'No (N)'	System	28 Sep 2020 17:02:43
	System	28 Sep 2020 17:02:43

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-28T12:02:10', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'c7725472-1c88-47cf-9fc5-761d1cfe1884' User entered '28 Sep 2020 12:02'	System	28 Sep 2020 17:02:43
	System	28 Sep 2020 17:02:43

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	27 Sep 2020 17:11:34
User entered 'Day 9'	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:44:11

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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-29T12:00:43', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd7981cf0-d409-4a6b-b473-d2406470c695'	System	29 Sep 2020 17:00:54
User entered 'No (N)'	System	29 Sep 2020 17:00:54

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:44:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-09-29T12:00:46', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'd7981cf0-d409-4a6b-b473-d2406470c695' User entered '29 Sep 2020 12:00'	System	29 Sep 2020 17:00:54
	System	29 Sep 2020 17:00:54

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:44:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:44:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:11:34

US3752129

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:26
	(b) (4)	
User entered 'No (N)'	Lauren Evans (b) (4)	15 Mar 2021 21:09:08

US3752129

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:26
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 21:09:08

US3752129

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:26
User entered empty.	(b) (4)	15 Mar 2021 21:09:08
	Lauren Evans (b) (4)	

US3752129

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:07:26
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	15 Mar 2021 21:09:08

US3752129

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:54:24

US3752129

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'I'	System	06 Oct 2020 12:54:24

US3752129

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:54:40

US3752129

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:54:40

US3752129

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:54:40

US3752129

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:54:40

US3752129

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4)	07 Oct 2020 22:46:39
	Amanda Horn (b) (4)	
	(b) (4)	

US3752129

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'I'	System	07 Oct 2020 22:46:39

US3752129

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:24:51

US3752129

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:24:51

US3752129

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:24:51

US3752129

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:24:51

US3752129

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:00:32

US3752129

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'I'	System	27 Oct 2020 21:00:32

US3752129

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:00:48

US3752129

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:00:48

US3752129

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[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 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:00:48

US3752129

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'VISIT3'	System	27 Oct 2020 21:00:48

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '08:28'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '26 Oct 2020 08:28'	System	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '60'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'bpm'	System	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'breaths/min'	System	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '126'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'mmHg'	System	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '80'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'mmHg'	System	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26

US3752129

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:35

US3752129

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:01:35

US3752129

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:02:20

US3752129

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:02:20

US3752129

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '08:29'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:02:20

US3752129

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered '26 Oct 2020 08:29'	System	27 Oct 2020 21:02:20

US3752129

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 21:02:24

US3752129

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'I'	System	27 Oct 2020 21:02:24

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 64'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-18T15:30:23', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'adffca57-4ed1-4d52-85d1-c1e2724c9bea'	System	18 Oct 2020 20:30:39
User entered 'Yes (Y)'	System	18 Oct 2020 20:30:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Have you been exposed to someone with 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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-18T15:30:26', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'adffca57-4ed1-4d52-85d1-c1e2724c9bea'	System	18 Oct 2020 20:30:39
User entered 'No (N)'	System	18 Oct 2020 20:30:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-18T15:30:29', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'adffca57-4ed1-4d52-85d1-c1e2724c9bea'	System	18 Oct 2020 20:30:39
User entered 'No (N)'	System	18 Oct 2020 20:30:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-18T15:30:32', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'adffca57-4ed1-4d52-85d1-c1e2724c9bea' User entered 'No (N)'	System	18 Oct 2020 20:30:39
	System	18 Oct 2020 20:30:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-18T15:30:36', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'adffca57-4ed1-4d52-85d1-c1e2724c9bea' User entered '18 Oct 2020 15:30:36'	System	18 Oct 2020 20:30:39
	System	18 Oct 2020 20:30:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 71'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-26T09:21:07', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '766902df-235e-4340-b4bf-8cbacb1494b0'	System	26 Oct 2020 14:21:39
User entered 'Yes (Y)'	System	26 Oct 2020 14:21:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Have you been exposed to someone with 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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-26T09:21:10', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '766902df-235e-4340-b4bf-8cbacb1494b0'	System	26 Oct 2020 14:21:39
User entered 'No (N)'	System	26 Oct 2020 14:21:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-26T09:21:13', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '766902df-235e-4340-b4bf-8cbacb1494b0'	System	26 Oct 2020 14:21:39
User entered 'No (N)'	System	26 Oct 2020 14:21:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-26T09:21:23', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '766902df-235e-4340-b4bf-8cbacb1494b0'	System	26 Oct 2020 14:21:39
User entered 'Yes (Y)'	System	26 Oct 2020 14:21:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-26T09:21:28', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '766902df-235e-4340-b4bf-8cbacb1494b0'	System	26 Oct 2020 14:21:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Oct 2020 14:21:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-26T09:21:31', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '766902df-235e-4340-b4bf-8cbacb1494b0' User entered '26 Oct 2020 09:21:31'	System	26 Oct 2020 14:21:39
	System	26 Oct 2020 14:21:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 78'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-11-01T16:32:30', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e4581fc1-6dc8-4536-a2f1-92931b1fb39e'	System	01 Nov 2020 22:32:37
User entered 'No (N)'	System	01 Nov 2020 22:32:37

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Have you been exposed to someone with 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 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-11-01T16:32:32', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e4581fc1-6dc8-4536-a2f1-92931b1fb39e'	System	01 Nov 2020 22:32:37
User entered 'No (N)'	System	01 Nov 2020 22:32:37

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-11-01T16:32:35', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e4581fc1-6dc8-4536-a2f1-92931b1fb39e' User entered '01 Nov 2020 16:32:35'	System	01 Nov 2020 22:32:37
	System	01 Nov 2020 22:32:37

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:44:02
Data entry locked.	System	18 Aug 2020 16:19:23
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55
Data entry locked.	System	18 Aug 2020 16:19:23
User entered 'Day 92'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55
Data entry locked.	System	18 Aug 2020 16:19:23
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 16:19:23

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:09:55
Data entry locked.	System	18 Aug 2020 16:19:23
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 16:19:23

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-04T10:07:53', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '13edd5db-8e5d-48c2-a6a2-d8f3ac0152d4'	System	04 Jan 2021 16:08:05
User entered 'No (N)'	System	04 Jan 2021 16:08:05

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-04T10:07:56', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '13edd5db-8e5d-48c2-a6a2-d8f3ac0152d4'	System	04 Jan 2021 16:08:05
User entered 'No (N)'	System	04 Jan 2021 16:08:05

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-04T10:08:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '13edd5db-8e5d-48c2-a6a2-d8f3ac0152d4' User entered '04 Jan 2021 10:08:00'	System	04 Jan 2021 16:08:05
	System	04 Jan 2021 16:08:05

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-09T12:00:43', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'da49460a-9890-489d-a4b7-feb42fc2d0d2'	System	09 Jan 2021 18:00:59
User entered 'No (N)'	System	09 Jan 2021 18:00:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-09T12:00:45', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'da49460a-9890-489d-a4b7-feb42fc2d0d2'	System	09 Jan 2021 18:00:59
User entered 'No (N)'	System	09 Jan 2021 18:00:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-09T12:00:48', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'da49460a-9890-489d-a4b7-feb42fc2d0d2'	System	09 Jan 2021 18:00:59
User entered '09 Jan 2021 12:00:48'	System	09 Jan 2021 18:00:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-18T11:59:11', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '87bab008-519b-45b6-9dd4-c831d969918d'	System	18 Jan 2021 17:59:18
User entered 'No (N)'	System	18 Jan 2021 17:59:18

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-18T11:59:13', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '87bab008-519b-45b6-9dd4-c831d969918d' User entered 'No (N)'	System	18 Jan 2021 17:59:18

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-18T11:59:16', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '87bab008-519b-45b6-9dd4-c831d969918d' User entered '18 Jan 2021 11:59:16'	System	18 Jan 2021 17:59:18
	System	18 Jan 2021 17:59:18

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-21T06:28:02', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a84dbf-101b-4a70-9807-994b818bc461'	System	21 Jan 2021 12:28:10
User entered 'No (N)'	System	21 Jan 2021 12:28:10

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-21T06:28:04', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a84dbf-101b-4a70-9807-994b818bc461'	System	21 Jan 2021 12:28:10
User entered 'No (N)'	System	21 Jan 2021 12:28:10

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-21T06:28:07', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '24a84dbf-101b-4a70-9807-994b818bc461' User entered '21 Jan 2021 06:28:07'	System	21 Jan 2021 12:28:10
	System	21 Jan 2021 12:28:10

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-29T11:47:46', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '393a9922-6a50-4f79-a5dd-9c12ae87cbb0' User entered 'No (N)'	System	29 Jan 2021 17:47:54
	System	29 Jan 2021 17:47:54

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-29T11:47:48', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '393a9922-6a50-4f79-a5dd-9c12ae87cbb0' User entered 'No (N)'	System	29 Jan 2021 17:47:54
	System	29 Jan 2021 17:47:54

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-01-29T11:47:51', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '393a9922-6a50-4f79-a5dd-9c12ae87cbb0' User entered '29 Jan 2021 11:47:51'	System	29 Jan 2021 17:47:54
	System	29 Jan 2021 17:47:54

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-06T13:39:15', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '637d6b88-6099-4dbd-b55b-98d0100aefd9' User entered 'No (N)'	System	06 Feb 2021 19:39:22
	System	06 Feb 2021 19:39:22

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-06T13:39:17', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '637d6b88-6099-4dbd-b55b-98d0100aefd9' User entered 'No (N)'	System	06 Feb 2021 19:39:22

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-06T13:39:19', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '637d6b88-6099-4dbd-b55b-98d0100aefd9' User entered '06 Feb 2021 13:39:19'	System	06 Feb 2021 19:39:22

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-13T12:00:12', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '4bb5a003-8483-484e-beca-e829688e084f' User entered 'No (N)'	System	13 Feb 2021 18:00:52
	System	13 Feb 2021 18:00:52

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-13T12:00:16', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '4bb5a003-8483-484e-beca-e829688e084f' User entered 'No (N)'	System	13 Feb 2021 18:00:52
	System	13 Feb 2021 18:00:52

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-13T12:00:23', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '4bb5a003-8483-484e-beca-e829688e084f' User entered '13 Feb 2021 12:00:23'	System	13 Feb 2021 18:00:52
	System	13 Feb 2021 18:00:52

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-21T17:59:13', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '227d2262-d223-49b9-a458-e82506490a52'	System	21 Feb 2021 23:59:21
User entered 'No (N)'	System	21 Feb 2021 23:59:21

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-21T17:59:15', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '227d2262-d223-49b9-a458-e82506490a52'	System	21 Feb 2021 23:59:21
User entered 'No (N)'	System	21 Feb 2021 23:59:21

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-21T17:59:18', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '227d2262-d223-49b9-a458-e82506490a52'	System	21 Feb 2021 23:59:21
User entered '21 Feb 2021 17:59:18'	System	21 Feb 2021 23:59:21

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-27T12:04:45-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '19608bb7-9981-48d0-abe6-bb4b39438cb7'	System	27 Feb 2021 18:08:50
User entered 'No (N)'	System	27 Feb 2021 18:08:50

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-27T12:04:47-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '19608bb7-9981-48d0-abe6-bb4b39438cb7'	System	27 Feb 2021 18:08:50
User entered 'No (N)'	System	27 Feb 2021 18:08:50

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-27T12:04:50-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '19608bb7-9981-48d0-abe6-bb4b39438cb7'	System	27 Feb 2021 18:08:50
User entered '27 Feb 2021 18:04:50'	System	27 Feb 2021 18:08:50

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-04T15:28:58-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e8da18e6-a6f6-44fb-adc1-7fb503bc88de'	System	13 Mar 2021 04:46:10
User entered 'No (N)'	System	13 Mar 2021 04:46:10

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-04T15:29:01-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e8da18e6-a6f6-44fb-adc1-7fb503bc88de'	System	13 Mar 2021 04:46:10
User entered 'No (N)'	System	13 Mar 2021 04:46:10

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-04T15:29:03-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'e8da18e6-a6f6-44fb-adc1-7fb503bc88de' User entered '04 Mar 2021 15:29:03'	System	13 Mar 2021 04:46:10
	System	13 Mar 2021 04:46:10

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-12T22:46:09-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '1c0a6ece-b572-44a3-93ef-9fd3e37a06e8'	System	18 Mar 2021 13:16:51
User entered 'No (N)'	System	18 Mar 2021 13:16:51

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-12T22:46:11-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '1c0a6ece-b572-44a3-93ef-9fd3e37a06e8'	System	18 Mar 2021 13:16:51
User entered 'No (N)'	System	18 Mar 2021 13:16:51

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-12T22:46:14-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '1c0a6ece-b572-44a3-93ef-9fd3e37a06e8'	System	18 Mar 2021 13:16:51
User entered '12 Mar 2021 22:46:14'	System	18 Mar 2021 13:16:51

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-18T08:16:50-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'eb964258-75af-4084-a7b8-353eba96837f'	System	28 Mar 2021 22:59:19
User entered 'No (N)'	System	28 Mar 2021 22:59:19

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-18T08:16:52-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'eb964258-75af-4084-a7b8-353eba96837f'	System	28 Mar 2021 22:59:19
User entered 'No (N)'	System	28 Mar 2021 22:59:19

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-18T08:16:57-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'eb964258-75af-4084-a7b8-353eba96837f'	System	28 Mar 2021 22:59:19
User entered '18 Mar 2021 08:16:57'	System	28 Mar 2021 22:59:19

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-28T17:59:21-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '842a63c2-3787-4b22-8752-2e7d455587f0'	System	28 Mar 2021 22:59:32
User entered 'No (N)'	System	28 Mar 2021 22:59:32

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-28T17:59:24-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '842a63c2-3787-4b22-8752-2e7d455587f0'	System	28 Mar 2021 22:59:32
User entered 'No (N)'	System	28 Mar 2021 22:59:32

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-03-28T17:59:26-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '842a63c2-3787-4b22-8752-2e7d455587f0'	System	28 Mar 2021 22:59:32
User entered '28 Mar 2021 17:59:26'	System	28 Mar 2021 22:59:32

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-02T11:02:58-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a5c5be55-f649-4c3d-8839-0261c09ab51d'	System	02 Apr 2021 16:08:29
User entered 'No (N)'	System	02 Apr 2021 16:08:29

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-02T11:03:00-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a5c5be55-f649-4c3d-8839-0261c09ab51d'	System	02 Apr 2021 16:08:29
User entered 'No (N)'	System	02 Apr 2021 16:08:29

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-02T11:03:03-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'a5c5be55-f649-4c3d-8839-0261c09ab51d'	System	02 Apr 2021 16:08:29
User entered '02 Apr 2021 11:03:03'	System	02 Apr 2021 16:08:29

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-11T18:23:06-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6f7dc93a-4d59-42f7-ba5c-b9a29a22005f' User entered 'No (N)'	System	11 Apr 2021 23:23:14
	System	11 Apr 2021 23:23:14

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-11T18:23:08-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6f7dc93a-4d59-42f7-ba5c-b9a29a22005f' User entered 'No (N)'	System	11 Apr 2021 23:23:14

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-11T18:23:10-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '6f7dc93a-4d59-42f7-ba5c-b9a29a22005f'	System	11 Apr 2021 23:23:14
User entered '11 Apr 2021 18:23:10'	System	11 Apr 2021 23:23:14

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-17T12:02:42-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7b3b083e-ed49-4dac-a74b-99238e81fe36'	System	17 Apr 2021 17:04:39
User entered 'No (N)'	System	17 Apr 2021 17:04:39

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-17T12:02:45-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7b3b083e-ed49-4dac-a74b-99238e81fe36'	System	17 Apr 2021 17:04:39
User entered 'No (N)'	System	17 Apr 2021 17:04:39

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-17T12:02:48-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '7b3b083e-ed49-4dac-a74b-99238e81fe36'	System	17 Apr 2021 17:04:39
User entered '17 Apr 2021 12:02:48'	System	17 Apr 2021 17:04:39

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-24T12:00:33-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '105d93c8-56f7-4c70-90ce-64c07a7b4844'	System	24 Apr 2021 17:00:49
User entered 'No (N)'	System	24 Apr 2021 17:00:49

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-24T12:00:35-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '105d93c8-56f7-4c70-90ce-64c07a7b4844'	System	24 Apr 2021 17:00:49
User entered 'No (N)'	System	24 Apr 2021 17:00:49

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-24T12:00:38-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '105d93c8-56f7-4c70-90ce-64c07a7b4844'	System	24 Apr 2021 17:00:49
User entered '24 Apr 2021 12:00:38'	System	24 Apr 2021 17:00:49

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-29T06:17:52-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '92fb72db-7960-4a87-bd2e-2e7fbb8345c8'	System	29 Apr 2021 11:18:22
User entered 'No (N)'	System	29 Apr 2021 11:18:22

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

Have you been exposed to someone with 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 (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-29T06:17:54-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '92fb72db-7960-4a87-bd2e-2e7fbb8345c8' User entered 'No (N)'	System	29 Apr 2021 11:18:22

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-04-29T06:17:56-05:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '92fb72db-7960-4a87-bd2e-2e7fbb8345c8'	System	29 Apr 2021 11:18:22
User entered '29 Apr 2021 06:17:56'	System	29 Apr 2021 11:18:22

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:09:55

US3752129

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:44:11

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-27T12:04:56-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '07b7f253-85be-429d-975c-23eb0265f9f1'	System	27 Feb 2021 18:09:27
User entered 'Yes (Y)'	System	27 Feb 2021 18:09:27

US3752129

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:44:11

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-27T12:05:04-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '07b7f253-85be-429d-975c-23eb0265f9f1'	System	27 Feb 2021 18:09:27
User entered 'No (N)'	System	27 Feb 2021 18:09:27

US3752129

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:44:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:44:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (828236BC-7A1E-4977-8E45-C1030E3058C8)', Time: '2021-02-27T12:05:09-06:00', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: '07b7f253-85be-429d-975c-23eb0265f9f1' User entered '27 Feb 2021 18:05:09'	System	27 Feb 2021 18:09:27
	System	27 Feb 2021 18:09:27

US3752129

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:18:19

US3752129

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:18:19

US3752129

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:18:19

US3752129

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:18:19

US3752129

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 18:18:26

US3752129

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:59:26
User entered 'I'	System	16 Nov 2020 18:18:26

US3752129

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4)	20 Jan 2021 17:12:27
	Amanda Horn (b) (4)	
	(b) (4)	

US3752129

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4)	20 Jan 2021 17:12:27
	Amanda Horn (b) (4)	
	(b) (4)	

US3752129

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4)	20 Jan 2021 17:12:27
	Amanda Horn (b) (4)	
	(b) (4)	

US3752129

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	20 Jan 2021 17:12:27
	(b) (4)	

US3752129

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:12:31
	Amanda Horn (b) (4)	
	(b) (4)	

US3752129

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered 'I'	System	20 Jan 2021 17:12:31

US3752129

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:12:40
	Amanda Horn (b) (4)	
	(b) (4)	

US3752129

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '19 Jan 2021'	(b) (4)	
	Amanda Horn (b) (4)	20 Jan 2021 17:12:40
	(b) (4)	

US3752129

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	20 Jan 2021 17:12:40

US3752129

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	20 Jan 2021 17:12:40
	(b) (4)	

US3752129

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4)	20 Jan 2021 17:12:44
	Amanda Horn (b) (4)	
	(b) (4)	

US3752129

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered 'I'	System	20 Jan 2021 17:12:44

US3752129

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 19:09:09
	Amanda Horn (b) (4)	
	(b) (4)	

US3752129

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '18 Feb 2021'	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 19:09:09
	(b) (4)	

US3752129

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Horn (b) (4) (b) (4)	24 Feb 2021 19:09:09

US3752129

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered empty.	(b) (4)	
	Amanda Horn (b) (4)	24 Feb 2021 19:09:09
	(b) (4)	

US3752129

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Yes (Y)'	(b) (4)	24 Feb 2021 19:09:16
	Amanda Horn (b) (4)	
	(b) (4)	

US3752129

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered 'I'	System	24 Feb 2021 19:09:16

US3752129

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:54:04

US3752129

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:54:04

US3752129

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:54:04

US3752129

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered 'VISIT4'	System	16 Mar 2021 13:54:04

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:14:51
User entered 'Yes (Y)'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:14:51
User entered '16 Mar 2021'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:14:51
User entered '08:05'	(b) (4)	
	Lauren Evans (b) (4)	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered '16 Mar 2021 08:05'	System	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:14:51
User entered '97.8' F	(b) (4)	
	Lauren Evans (b) (4)	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:14:51
User entered 'Oral (Oral)'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:14:51
User entered empty.	(b) (4)	
	Lauren Evans (b) (4)	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:14:51
User entered '48'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered 'bpm'	System	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:14:51
User entered '14'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered 'breaths/min'	System	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:14:51
User entered '102'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered 'mmHg'	System	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:14:51
User entered '74'	(b) (4) Lauren Evans (b) (4)	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered 'mmHg'	System	30 Mar 2021 17:53:30

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53

US3752129

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53

US3752129

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:54:21

US3752129

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:54:21

US3752129

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:07:06

US3752129

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:07:06

US3752129

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered '08:14'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:07:06

US3752129

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered '16 Mar 2021 08:14'	System	16 Mar 2021 14:07:06

US3752129

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:07:10

US3752129

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:02:53
User entered 'I'	System	16 Mar 2021 14:07:10

US3752129

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:13:01
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	19 Apr 2021 19:43:15
	(b) (4)	

US3752129

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:13:01
	(b) (4)	
User entered '19 Apr 2021'	Timothy Campbell (b) (4)	19 Apr 2021 19:43:15
	(b) (4)	

US3752129

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:13:01
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Timothy Campbell (b) (4)	19 Apr 2021 19:43:15
	(b) (4)	

US3752129

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:13:01
	(b) (4)	
User entered empty.	Timothy Campbell (b) (4)	19 Apr 2021 19:43:15
	(b) (4)	

US3752129

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	21 Apr 2021 00:13:01
	(b) (4)	
User entered 'Yes (Y)'	Timothy Campbell (b) (4)	19 Apr 2021 19:43:23
	(b) (4)	

US3752129

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 19:43:23

US3752129

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

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:25:54

US3752129

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

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:25:54

US3752129

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

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:25:54

US3752129

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

Form: Visit Date

Generated On: 10 Jun 2021 09:44:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 22:25:54

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:16

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:17:13
User entered '0'	(b) (4) Lauren Evans (b) (4)	10 Mar 2021 16:49:48
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:31:04

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:16

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:17:13
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	10 Mar 2021 16:49:48
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:31:04

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:16

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:16

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 02:34:27
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 22:26:16

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 02:34:27
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	18 Jan 2021 22:26:16

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:16

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered empty.	System	18 Jan 2021 22:26:16

US3752129

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

Form: Unblinding

Generated On: 10 Jun 2021 09:44:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered empty.	System	18 Jan 2021 22:26:16

US3752129

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:36

US3752129

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:36

US3752129

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '16:05'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:36

US3752129

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered '18 Jan 2021 16:05'	System	18 Jan 2021 22:26:36

US3752129

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:44:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:46

US3752129

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:44:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:46

US3752129

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:44:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '16:01'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:26:46

US3752129

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:00
User entered '18 Jan 2021 16:01'	System	18 Jan 2021 22:26:46

US3752129

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:44:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:39:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:42:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:53:59
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:35:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:27
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 16:56:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 16:56:21
	(b) (4)	
Data point term sent to Coder	System	13 Oct 2020 16:55:27
User entered 'PAIN AT INJECTION SITE'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:29
User entered 'No (N)'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:31
User entered 'Yes (Y)'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:33
User entered 'No (N)'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:37
User entered '21 Sep 2020'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 17:43:46
Query 'Data is required. Please provide.' answered with 'UNKNOWN START TIME' (Site from System).	Amanda Horn (b) (4)	13 Oct 2020 16:55:17
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 16:54:56
User entered empty.	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User entered empty.	System	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:51
User entered 'No (N)'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User closed query 'Per source, this ended on 02OCT2020. Please correct in EDC.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 16:10:27
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 16:10:24
Query 'Per source, this ended on 02OCT2020. Please correct in EDC.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:06:32
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 20:06:24
User opened query 'Per source, this ended on 02OCT2020. Please correct in EDC.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:05:32
User entered '29 Sep 2020'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 17:43:56
Query 'Data is required. Please provide.' answered with 'UNKNOWN END TIME' (Site from System).	Amanda Horn (b) (4)	13 Oct 2020 16:55:24
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 16:54:56
User entered empty.	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User entered empty.	System	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:51
User entered 'No (N)'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:55
User entered '0'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:57
User entered '0'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:00
User entered '0'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:03
User entered empty.	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:06
User entered empty.	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:08
User entered empty.	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:09
User entered empty.	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:11
User entered '0'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:13
User entered '0'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:15
User entered '0'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'Related (RELATED)'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'Related (RELATED)'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'None (NONE)'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Un-verified.	Amanda Horn (b) (4)	18 Nov 2020 15:55:16
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Amanda Horn (b) (4)	18 Nov 2020 15:55:16
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:08:13
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Nov 2020 16:17:56
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:17:56
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Nov 2020 16:17:49
User entered '0'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	19 Nov 2020 17:14:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:56:48
DataPoint Un-verified.	Amanda Horn (b) (4)	18 Nov 2020 15:55:16
User entered '1' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 15:55:16
DataPoint Verified.	Amanda Horn (b) (4)	16 Nov 2020 16:11:12
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:18:02
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:17:49
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:42:26
User entered '1'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:08:21
User entered '0'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:08:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:08:25
User entered empty.	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:08:28
User entered empty.	Amanda Horn (b) (4)	13 Oct 2020 16:54:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User entered '0'	System	13 Oct 2020 16:54:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21
User entered '0'	System	13 Oct 2020 16:54:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:21

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:21
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 18:21:19
User entered 'USA-US113-2020-mRNA-1273-P301000010'	(b) (4), (b) (6)	17 Nov 2020 18:21:02

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of THYROID CARCINOMA noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:46:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Papillary thyroid cancer, LLT: Thyroid papillary carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:56:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Dec 2020 18:56:43
Data point term sent to Coder	System	18 Dec 2020 18:40:04
Query 'Per DM CLR: Please confirm if this AE is a worsening of THYROID CARCINOMA noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:39:19
Coding entries removed.	(b) (4), (b) (6)	18 Dec 2020 18:39:10
User entered 'PAPILLARY THYROID CARCINOMA exacerbation' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 18:39:10
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of THYROID CARCINOMA noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 12:24:20

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Papillary thyroid cancer, LLT: Thyroid papillary carcinoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:19:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:19:50
Data point term sent to Coder	System	17 Nov 2020 17:19:28
User entered 'Papillary thyroid carcinoma'	(b) (4), (b) (6) (b) (4)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:25
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:27
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:45
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:48
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:50
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	18 Dec 2020 18:43:22
User entered 'No (N)' reason for change: Data Entry Error	System	18 Dec 2020 18:43:22
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	18 Dec 2020 18:41:38
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 17:19:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 17:19:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:19:34
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 17:19:12
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
	(b) (4)	
User closed query 'please verify end date per date of surgery and update AE log' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 16:12:32
Query 'please verify end date per date of surgery and update AE log' answered with 'End date corrected to 02 OCT 2020 per surgery date.' (Site from CRA).	Haylee Rowe (b) (4)	10 Mar 2021 14:58:57
Signature has been broken.	(b) (4)	
	Haylee Rowe (b) (4)	10 Mar 2021 14:58:34
	(b) (4)	
User entered '02 Oct 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4)	10 Mar 2021 14:58:34
	(b) (4)	
User opened query 'please verify end date per date of surgery and update AE log' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 17:46:52
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 17:46:00
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:52
	(b) (4), (b) (6)	
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User closed query 'Per DM CLR: Please review the End date of this AE as the corresponding procedure of Thyroidectomy was performed on 02 Oct 2020. However, the End date of this AE is 01 Oct 2020. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 09:33:22
Query 'Per DM CLR: Please review the End date of this AE as the corresponding procedure of Thyroidectomy was performed on 02 Oct 2020. However, the End date of this AE is 01 Oct 2020. Please reconcile and update accordingly. Otherwise, clarify.' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4)	01 Feb 2021 15:16:43
	(b) (4)	
User opened query 'Per DM CLR: Please review the End date of this AE as the corresponding procedure of Thyroidectomy was performed on 02 Oct 2020. However, the End date of this AE is 01 Oct 2020. Please reconcile and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 03:42:46
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the papillary thyroid carcinoma event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:01:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the papillary thyroid carcinoma event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Papillary carcinoma removed by thyroidectomy.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 18:43:01
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 18:41:38
User opened query 'PV Query: Please provide the papillary thyroid carcinoma event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:51:54
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Grade 4 (Grade 4)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:44:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
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)	17 Nov 2020 17:23:46
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	17 Nov 2020 17:19:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:01
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:05
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
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)	17 Nov 2020 17:27:21
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		17 Nov 2020 17:27:21
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	17 Nov 2020 17:23:46
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:23:46
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:27:02
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:10
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'PV Query: Please clarify hospital discharge date for event term of Papillary Thyroid Carcinoma. Discharge date for event of Total thyroidectomy is reported as 03 Oct 2020. Discharge date for event Papillary thyroid carcinoma is reported as 02 Oct 2020.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:55:49
Query 'PV Query: Please clarify hospital discharge date for event term of Papillary Thyroid Carcinoma. Discharge date for event of Total thyroidectomy is reported as 03 Oct 2020. Discharge date for event Papillary thyroid carcinoma is reported as 02 Oct 2020.' answered with 'corrected' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:52:51
User entered '03 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:52:34
User opened query 'PV Query: Please clarify hospital discharge date for event term of Papillary Thyroid Carcinoma. Discharge date for event of Total thyroidectomy is reported as 03 Oct 2020. Discharge date for event Papillary thyroid carcinoma is reported as 02 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:51:42
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:27:02
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:13
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:27:21
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:18
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:22
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:24
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:26
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	28 Dec 2020 22:17:15
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:28
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please confirm no Concomitant Medication was given for this AE.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 20:37:25
Query 'Per CDM: Please confirm no Concomitant Medication was given for this AE.' answered with 'No con med given. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	24 Mar 2021 14:54:00
User opened query 'Per CDM: Please confirm no Concomitant Medication was given for this AE.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 14:46:54
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:30:43
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:33
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:36
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query 'PV Query: Please provide the final event outcome for event papillary thyroid carcinoma, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:01:09
Query 'PV Query: Please provide the final event outcome for event papillary thyroid carcinoma, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 18:43:39
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 18:41:38
User opened query 'PV Query: Please provide the final event outcome for event papillary thyroid carcinoma, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:52:09
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:38
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:45:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User closed query ' PV Query: Please provide date for total thyroidectomy. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 13:57:35
Query ' PV Query: Please provide date for total thyroidectomy. ' answered with 'added' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 20:42:44
User entered 'SUBJECT HAD LEFT THYROID FINE NEEDLE ASPIRATION AND BIOPSY WHICH WAS MALIGNANT, RESULTING IN TOTAL THYROIDECTOMY 02OCT2020.' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 20:42:38
User closed query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with study drug from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 16:14:32
Query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with study drug from none to not applicable. ' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 22:17:24
User opened query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with study drug from none to not applicable. ' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 15:34:25
User opened query ' PV Query: Please provide date for total thyroidectomy. ' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 15:33:35
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)	21 Dec 2020 15:01:18
User closed query 'PV Query: Thank you for adding papillary thyroid carcinoma as an SAE. Please consider removing thyroidectomy as a separate SAE since it was performed for the event of papillary thyroid carcinoma' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 15:01:15

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Narrative](#)

Audit	User	Time (GMT)
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 'Subject was not retested for COVID19 as she had been tested prior to hospital admission.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 18:45:09
Query 'PV Query: Thank you for adding papillary thyroid carcinoma as an SAE. Please consider removing thyroidectomy as a separate SAE since it was performed for the event of papillary thyroid carcinoma' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 18:41:08
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)	04 Dec 2020 16:47:43
User opened query 'PV Query: Thank you for adding papillary thyroid carcinoma as an SAE. Please consider removing thyroidectomy as a separate SAE since it was performed for the event of papillary thyroid carcinoma' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 16:47:26
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Nov 2020 17:23:46
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	17 Nov 2020 17:23:46
User entered 'Subject had left thyroid fine needle aspiration and biopsy which was malignant, resulting in total thyroidectomy.' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:23:46
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	17 Nov 2020 17:19:12
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Nov 2020 17:19:12

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:44:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 17:27:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Bone, calcium, magnesium and phosphorus metabolism disorders, HLT: Calcium metabolism disorders, PT: Hypocalcaemia, LLT: Hypocalcemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 17:31:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 17:31:00
	(b) (4)	
Data point term sent to Coder	System	17 Nov 2020 17:29:37
User entered 'Hypocalcemia'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '02 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User entered empty.	System	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 14:07:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 14:07:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 16:04:28
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'has not resolved as still taking calcium carbonate' (Site from DM).	Jamie Pettus (b) (4)	19 Jan 2021 19:37:08
	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 06:18:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 14:07:59
User entered '20 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 14:07:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User entered empty.	System	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 14:07:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	16 Mar 2021 14:07:59
Data Entry Error		
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User entered '0'	System	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29
User entered '1'	System	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:44:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:26:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:39:48
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 11:45:53
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'At this time, no dermal fillers and/or botox to document for this subject' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	23 Mar 2021 20:33:19
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:01:31
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User closed query 'Concomitant Medication box was checked for event "TOTAL THYROIDECTOMY" however medication is not present for this event. Please update.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 18:55:07
Query 'Concomitant Medication box was checked for event "TOTAL THYROIDECTOMY" however medication is not present for this event. Please update.' answered with 'Levoxyl is listed for condition of hypothyroidism which is a result of total thyroidectomy.' (Site from CRA).	(b) (4), (b) (6)	28 Dec 2020 22:18:16

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:44:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Concomitant Medication box was checked for event "TOTAL THYROIDECTOMY" however medication is not present for this event. Please update.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:48:51
	(b) (4), (b) (6)	12 Nov 2020 15:45:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:35:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 21:09:52
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	11 Jan 2021 19:13:44
	Jamie Pettus (b) (4)	11 Jan 2021 19:12:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 15:46:19
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: MIRENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 19:34:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	22 Aug 2020 19:34:18
User entered 'Mirena IUD'	(b) (4)	
	System	19 Aug 2020 13:38:09
	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 15:38:15
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:25
User entered 'Contraceptive'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:27
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 15:38:15
User entered 'unknown'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:33
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:35
User entered 'DEVICE' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 21:03:49
User entered 'Devoce' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 15:38:15
User entered 'unknown'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User closed query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 19:24:17
Query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:16:21
User opened query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:52:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:37
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 15:38:15
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:40
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4)	13 Jan 2021 18:32:44
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4)	11 Jan 2021 19:13:04
DataPoint Un-verified.	Jamie Pettus (b) (4)	11 Jan 2021 19:12:56
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	11 Jan 2021 19:12:56
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:24:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:41
User entered 'Vaginal (VAGINAL)'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Un-verified.	Jamie Pettus (b) (4)	11 Jan 2021 19:12:56
	(b) (4)	
User entered 'uterine via vagina' reason for change:	Jamie Pettus (b) (4)	11 Jan 2021 19:12:56
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:43
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:48
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:16:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 13:37:13
User entered 'un UNK 2019'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:49
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:16:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 16:16:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:16:13
User entered 'un UNK 2019' reason for change:	(b) (4), (b) (6)	17 Nov 2020 16:16:13
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:52
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:46:56
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User entered empty.	System	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User entered empty.	System	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:40:30
User entered empty.	System	19 Aug 2020 13:37:13

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: LEVOXYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 17:26:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 17:26:01
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 17:25:12
Coding entries removed.	Jamie Pettus (b) (4)	22 Feb 2021 17:24:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:48:16
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: LEVOXYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:05:25
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 21:05:25
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 21:04:08
User entered 'Levoxyl'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:48:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 16:19:05
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	22 Feb 2021 17:24:59
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	22 Feb 2021 17:24:49
User entered 'HYPOTHYROIDISM due to thyroid cancer' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	22 Feb 2021 17:24:49
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 19:30:43
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:48:20
User entered 'Hypothyroidism'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:48:22
User entered '100'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:32:50
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 19:14:58
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 19:14:29
User entered 'ug (ug)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 19:14:29
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:24:54
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:48:25
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:48:27
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:48:29
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:48:31
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 15:48:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:48:35
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:49:18
User entered '26 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:49:20
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:49:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:49:24
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:49:27
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 21:03:35

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Nov 2020 08:05:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 08:05:02
Data point term sent to Coder	System	17 Nov 2020 17:11:19
User entered 'Doxycycline'	(b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Post procedure infection prophylaxis'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '100'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User entered '2'	System	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User entered '1'	System	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User entered '804 (804)'	System	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM CARBONATE;COLECALCIFEROL, PRODUCTSYNONYM: CALCIUM CARBONATE/VITAMIN D3 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Nov 2020 08:08:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 08:08:04
Data point term sent to Coder	System	17 Nov 2020 17:12:22
User entered 'Calcium carbonate with vitamin D3'	(b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Hypocalcemia'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:03:28
' (Site from DM).		
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 15:20:03
' answered with 'data updated' (Site from DM).		
User entered '500/600' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 15:19:54
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	(b) (4), (b) (6)	27 Jan 2021 09:05:37
' (Site from DM).		
User entered '600'	(b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Jamie Pettus (b) (4)	01 Feb 2021 15:19:54
Data Entry Error	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
User entered 'mg/IU' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Feb 2021 15:19:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:59:27
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: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:14:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:14:47
Data point term sent to Coder	System	17 Nov 2020 17:14:24
User entered 'Aleve'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:59:32
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:59:33
User entered 'Injection site pain'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:59:35
User entered '440'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:59:37
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:00:29
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:00:31
User entered 'as needed (PRN)'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:00:33
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:00:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:00:39
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:00:45
User entered '22 Sep 2020'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:00:46
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:00:48
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:00:51
User entered '22 Sep 2020'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:01:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User entered empty.	System	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User entered empty.	System	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:11
User entered empty.	System	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
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)	18 Jan 2021 22:30:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Jan 2021 22:30:12
Data point term sent to Coder	System	18 Jan 2021 22:28:58
User entered 'Influenza vaccine'	(b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Influenza prophylaxis'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '0.5'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered '21 Oct 2020'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User signature succeeded.	Priyantha Wijewardane	06 Mar 2021 00:26:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User entered empty.	System	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User entered empty.	System	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:15
User entered empty.	System	18 Jan 2021 22:28:42

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Mar 2021 14:10:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 14:10:50
Data point term sent to Coder	System	16 Mar 2021 14:10:33
User entered 'tetanus booster'	(b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'tetanus prophylaxis'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered '0.5'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered empty.	(b) (4)	16 Mar 2021 14:09:39
	(b) (4), (b) (6)	

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:26:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User entered empty.	System	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User entered empty.	System	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:18
User entered empty.	System	16 Mar 2021 14:09:39

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Mar 2021 12:09:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 12:09:31
Data point term sent to Coder	System	24 Mar 2021 15:15:24
User entered 'BOTOX'	Haylee Rowe (b) (4) (b) (4)	24 Mar 2021 15:14:56

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered 'No (N)'	(b) (4)	24 Mar 2021 15:14:56
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered 'COSMETIC ELECTIVE'	Haylee Rowe (b) (4)	24 Mar 2021 15:14:56

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered '10'	Haylee Rowe (b) (4)	24 Mar 2021 15:14:56

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered 'IU (IU)'	Haylee Rowe (b) (4)	24 Mar 2021 15:14:56

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered empty.	(b) (4)	24 Mar 2021 15:14:56
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered 'once (ONCE)'	(b) (4)	24 Mar 2021 15:14:56
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered empty.	(b) (4)	24 Mar 2021 15:14:56
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered 'Subcutaneous (SUBCUTANEOUS)'	Haylee Rowe (b) (4)	24 Mar 2021 15:14:56

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered empty.	(b) (4)	24 Mar 2021 15:14:56
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered '12 Feb 2021'	(b) (4)	
	Haylee Rowe (b) (4)	24 Mar 2021 15:14:56
	(b) (4)	

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered '0'	Haylee Rowe (b) (4)	24 Mar 2021 15:14:56

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered 'No (N)'	(b) (4)	24 Mar 2021 15:14:56
	Haylee Rowe (b) (4)	
	(b) (4)	

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered '12 Feb 2021'	(b) (4)	
	Haylee Rowe (b) (4)	24 Mar 2021 15:14:56
	(b) (4)	

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User signature succeeded.	Priyantha Wijewardane	25 Mar 2021 18:36:30
User entered 'No (N)'	Haylee Rowe (b) (4)	24 Mar 2021 15:14:56

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User entered empty.	System	24 Mar 2021 15:14:56

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User entered empty.	System	24 Mar 2021 15:14:56

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:27:21
User entered empty.	System	24 Mar 2021 15:14:56

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:44:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:39:48
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 17:43:49
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:30:05

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:44:11

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '28 Aug 2020'	(b) (4), (b) (6)	17 Nov 2020 17:31:20

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:44:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Left thyroid fine needle aspiration with biopsy'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:31:20

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Medical History (MH)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:31:20

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:44:11

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:31:20

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:44:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '02 Oct 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:31:58

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:44:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Total thyroidectomy'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:31:58

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:31:58

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:44:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:31:58

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:44:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:38

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:44:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Thyroid cancer ablation with I-131'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:38

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:38

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:44:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:16
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:32:38

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:44:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '04 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:00

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:44:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Total body iodine scan'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:00

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:44:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:00

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:44:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:28:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 17:33:00

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:22
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'USA-US113-2020-MRNA-1273-P301000010'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:34
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:39
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:47
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:54
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Priyantha'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:55
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Wijewardane'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:58
User entered '9601 Baptist Health Drive Suite 310'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:00
User entered 'Little Rock'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:02
User entered 'AR'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:03
User entered '72205'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:05
User entered 'US'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	11 Mar 2021 16:54:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '6'	System	04 Jan 2021 13:58:21
User entered '5'	System	29 Dec 2020 16:15:11
User entered '4'	System	21 Dec 2020 15:18:17
User entered '3'	System	25 Nov 2020 20:56:31
User entered '2'	System	17 Nov 2020 18:22:48
User entered '1'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:22
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'USA-US113-2020-MRNA-1273-P301000010'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:34
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:39
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:47
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:54
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Priyantha'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:55
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Wijewardane'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:58
User entered '9601 Baptist Health Drive Suite 310'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:00
User entered 'Little Rock'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:02
User entered 'AR'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:03
User entered '72205'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:05
User entered 'US'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	11 Mar 2021 16:54:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '6'	System	04 Jan 2021 13:58:21
User entered '5'	System	29 Dec 2020 16:15:11
User entered '4'	System	21 Dec 2020 15:18:17
User entered '3'	System	25 Nov 2020 20:56:31
User entered '2'	System	17 Nov 2020 18:22:48
User entered '1'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:44:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:42:18
User entered '10/Nov/2020 15:39'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:44:11

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.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:20
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:22
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'USA-US113-2020-MRNA-1273-P301000010'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:34
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:39
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:47
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:54
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Priyantha'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:55
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Wijewardane'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:58
User entered '9601 Baptist Health Drive Suite 310'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:00
User entered 'Little Rock'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:02
User entered 'AR'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:03
User entered '72205'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:05
User entered 'US'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	11 Mar 2021 16:54:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '6'	System	04 Jan 2021 13:58:21
User entered '5'	System	29 Dec 2020 16:15:11
User entered '4'	System	21 Dec 2020 15:18:17
User entered '3'	System	25 Nov 2020 20:56:31
User entered '2'	System	17 Nov 2020 18:22:48
User entered '1'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:44:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '17/Nov/2020 18:22'	System	17 Nov 2020 18:22:48

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:44:11

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.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 20:56:00
User entered 'I'	(b) (4), (b) (6)	17 Nov 2020 18:22:48

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:22
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'USA-US113-2020-MRNA-1273-P301000010'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:34
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:39
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:47
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:54
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Priyantha'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:55
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Wijewardane'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:58
User entered '9601 Baptist Health Drive Suite 310'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:00
User entered 'Little Rock'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:02
User entered 'AR'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:03
User entered '72205'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:05
User entered 'US'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	11 Mar 2021 16:54:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '6'	System	04 Jan 2021 13:58:21
User entered '5'	System	29 Dec 2020 16:15:11
User entered '4'	System	21 Dec 2020 15:18:17
User entered '3'	System	25 Nov 2020 20:56:31
User entered '2'	System	17 Nov 2020 18:22:48
User entered '1'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:44:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '25/Nov/2020 20:56'	System	25 Nov 2020 20:56:31

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:44:11

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.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:18:01
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 20:56:31

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:22
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'USA-US113-2020-MRNA-1273-P301000010'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:34
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:39
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:47
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:54
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Priyantha'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:55
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Wijewardane'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:58
User entered '9601 Baptist Health Drive Suite 310'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:00
User entered 'Little Rock'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:02
User entered 'AR'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:03
User entered '72205'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:05
User entered 'US'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	11 Mar 2021 16:54:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '6'	System	04 Jan 2021 13:58:21
User entered '5'	System	29 Dec 2020 16:15:11
User entered '4'	System	21 Dec 2020 15:18:17
User entered '3'	System	25 Nov 2020 20:56:31
User entered '2'	System	17 Nov 2020 18:22:48
User entered '1'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:44:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered '21/Dec/2020 10:18'	(b) (4) System	21 Dec 2020 15:18:17

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:44:11

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.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	29 Dec 2020 16:14:51
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 15:18:17

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:22
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'USA-US113-2020-MRNA-1273-P301000010'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:34
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:39
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:47
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:54
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Priyantha'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:55
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Wijewardane'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:58
User entered '9601 Baptist Health Drive Suite 310'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:00
User entered 'Little Rock'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:02
User entered 'AR'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:03
User entered '72205'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:05
User entered 'US'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	11 Mar 2021 16:54:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '6'	System	04 Jan 2021 13:58:21
User entered '5'	System	29 Dec 2020 16:15:11
User entered '4'	System	21 Dec 2020 15:18:17
User entered '3'	System	25 Nov 2020 20:56:31
User entered '2'	System	17 Nov 2020 18:22:48
User entered '1'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:44:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '29/Dec/2020 11:15'	System	29 Dec 2020 16:15:11

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:44:11

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.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 13:57:57
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 16:15:11

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:22
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'USA-US113-2020-MRNA-1273-P301000010'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:34
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:39
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:47
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:54
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Priyantha'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:55
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Wijewardane'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:58
User entered '9601 Baptist Health Drive Suite 310'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:00
User entered 'Little Rock'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:02
User entered 'AR'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:03
User entered '72205'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:05
User entered 'US'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	11 Mar 2021 16:54:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '6'	System	04 Jan 2021 13:58:21
User entered '5'	System	29 Dec 2020 16:15:11
User entered '4'	System	21 Dec 2020 15:18:17
User entered '3'	System	25 Nov 2020 20:56:31
User entered '2'	System	17 Nov 2020 18:22:48
User entered '1'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:44:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '04/Jan/2021 13:58'	System	04 Jan 2021 13:58:21

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:44:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 16:53:23
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Jan 2021 13:58:21

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:22
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'USA-US113-2020-MRNA-1273-P301000010'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:26
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:30
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:32
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:34
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Yes (Y)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:39
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:47
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'No (N)'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:54
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Priyantha'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:41:55
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:46
User entered 'Wijewardane'	System	10 Nov 2020 15:39:19

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:58
User entered '9601 Baptist Health Drive Suite 310'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:00
User entered 'Little Rock'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:02
User entered 'AR'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Un-verified.	System	17 Nov 2020 17:38:24
User entered empty.	System	17 Nov 2020 17:38:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:03
User entered '72205'	(b) (4), (b) (6)	10 Nov 2020 15:58:38

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 18:22:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:05
User entered 'US'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	11 Mar 2021 16:54:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:30:43
	(b) (4)	
User entered '6'	System	04 Jan 2021 13:58:21
User entered '5'	System	29 Dec 2020 16:15:11
User entered '4'	System	21 Dec 2020 15:18:17
User entered '3'	System	25 Nov 2020 20:56:31
User entered '2'	System	17 Nov 2020 18:22:48
User entered '1'	System	10 Nov 2020 15:39:56

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:44:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:17:13
	(b) (4)	
User entered '11/Mar/2021 10:54'	System	11 Mar 2021 16:54:04

US3752129

Folder: SAE USA-US113-2020-MRNA-1273-P301000010

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:44:11

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.	Priyantha Wijewardane	12 Mar 2021 16:17:13
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 16:54:04