

US3752129 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:14:40

All time stamps listed in this document are displayed in GMT

US3752129

Form: Participant Creation

Generated On: 26 Nov 2020 11:14:40

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

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 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:14:40

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:14:40

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:40

Condition	THYROID CARCINOMA
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☒
	No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	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

Generated On: 26 Nov 2020 11:14:40

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

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

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Folder: Screening

Form: Risk of Exposure

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

Generated On: 26 Nov 2020 11:14:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	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 ☒ Axillary ☐ Other ☐
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)

Generated On: 26 Nov 2020 11:14:40

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	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 ☒ Axillary ☐ Other ☐
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

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Was the sample collected?

Yes ☒

No ☐

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

Generated On: 26 Nov 2020 11:14:40

Collection date (<i>dd MMM yyyy</i>)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 11:14:40

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

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

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Yes ☐	
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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
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

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

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

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

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

US3752129

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	26 OCT 2020
Collection time (<i>00:00-23:59</i>)	08:29 (24 HR)
Collection date and time (derived)	26 OCT 2020 08:29

US3752129

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Date and time of submission	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: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	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: 26 Nov 2020 11:14:40

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: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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23 NOV 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 117

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2020 00:01

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28 DEC 2020 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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14 JAN 2021 00:01

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18 JAN 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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25 JAN 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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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: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 187

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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18 FEB 2021 00:01

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22 FEB 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

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01 MAR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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08 MAR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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15 MAR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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22 MAR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

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29 MAR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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22 APR 2021 00:01

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26 APR 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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07 MAR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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21 MAR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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04 APR 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

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09 MAY 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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°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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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06 JUN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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13 JUN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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°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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

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20 JUN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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23 JUN 2022 00:01

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27 JUN 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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

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04 JUL 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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07 JUL 2022 00:01

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11 JUL 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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14 JUL 2022 00:01

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18 JUL 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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21 JUL 2022 00:01

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25 JUL 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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01 AUG 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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04 AUG 2022 00:01

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08 AUG 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

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11 AUG 2022 00:01

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15 AUG 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 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: 26 Nov 2020 11:14:40

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3752129

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752129

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3752129

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:14:40

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

US3752129

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:14:40

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3752129

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:14:40

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)

Generated On: 26 Nov 2020 11:14:40

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	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

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

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

AEID	USA-US113-2020-MRNA-1273-P30 1000010
Adverse event	TOTAL THYROIDECTOMY
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)	02 OCT 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	True
Hospital Admission Date (dd MMM yyyy)	02 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	03 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	343 of 1768

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT ADMITTED TO HOSPITAL FOR THYROIDECTOMY. ADMISSION LESS THAN 24HOURS
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☒
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAD LEFT THYROID FINE NEEDLE ASPIRATION AND BIOPSY WHICH WAS MALIGNANT, RESULTING IN TOTAL THYROIDECTOMY.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

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

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:14:40

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)

Generated On: 26 Nov 2020 11:14:40

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 ☐ Intramuscular ☐

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☒
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) UN UNK 2019		
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:40

Name of Medication	LEVOXYL
Prophylaxis	Yes ☐ No ☒
Indication	HYPOTHYROIDISM
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:14:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:40

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 ☐ Intraocular ☐

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:40

Name of Medication	CALCIUM CARBONATE WITH VITAMIN D3
Prophylaxis	Yes ☐ No ☒
Indication	HYPOCALCEMIA
Dose per administration	600
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☒ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:40

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:40

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 ☐ Intramuscular ☐

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:14:40

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		22 SEP 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:14:40

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:14:40

Procedure/Surgery date (<i>dd MMM yyyy</i>)	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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

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

Generated On: 26 Nov 2020 11:14:40

SAEID	USA-US113-2020-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	2

US3752129

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:14:40

SAEID	USA-US113-2020-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	2
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)

Generated On: 26 Nov 2020 11:14:40

SAEID	USA-US113-2020-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	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)	2
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

Audit

US3752129 (Prod: Baptist Health Center for Clinical Research)

US3752129

Form: Participant Creation

Generated On: 26 Nov 2020 11:14:40

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3752129'	RWS_ENDPOINT ENDPOINT (b) (4) 	18 Aug 2020 15:10:37

US3752129

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 16:18:37

US3752129

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	18 Aug 2020 15:10:38

US3752129

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Aug 2020 16:18:37

US3752129

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	18 Aug 2020 16:18:37

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1974'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	18 Aug 2020 15:10:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Age](#)

Audit	User	Time (GMT)
User entered '46'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '46'	System	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:14:40

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:21:39

US3752129

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '2020'	System	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 16:18:55

US3752129

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	18 Aug 2020 15:10:38

US3752129

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:14:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 16:19:01

US3752129

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 16:19:01

US3752129

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:14:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(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: 26 Nov 2020 11:14:40

[Condition](#)

Audit	User	Time (GMT)
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
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
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
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

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:40

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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 '1'	(b) (4), (b) (6)	19 Aug 2020 13:32:43

US3752129

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:14:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '10:15'	(b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '18 Aug 2020 10:15'	System	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '067.5' in	(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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '175.0' lb	(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: 26 Nov 2020 11:14:40

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 13:23:35

US3752129

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(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: 26 Nov 2020 11:14:40

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020' reason for change: Data Entry Error	(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: 26 Nov 2020 11:14:40

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:40

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:40

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:40

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:40

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:40

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:40

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:14:40

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:24:13

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Date of test \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 13:24:32

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

[Specify](#)

Audit	User	Time (GMT)
User entered 'Husband is a physician who sees patients'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

[Other](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:14:40

[Specify](#)

Audit	User	Time (GMT)
User entered 'Resides in a community with ongoing person to person transmission'	(b) (4), (b) (6)	19 Aug 2020 13:27:04

US3752129

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:27:30

US3752129

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:27:30

US3752129

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Aug 2020 13:27:30

US3752129

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	19 Aug 2020 13:27:30

US3752129

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	18 Aug 2020 16:04:39

US3752129

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:40

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	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) [REDACTED]	18 Aug 2020 16:04:39

US3752129

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	18 Aug 2020 16:04:39

US3752129

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:46

US3752129

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:46

US3752129

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:46

US3752129

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:46

US3752129

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:40

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:27:46

US3752129

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	(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

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:14:40

[Height](#)

Audit	User	Time (GMT)
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) (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.'	(b) (4), (b) (6)	15 Sep 2020 13:53:32
answered with 'updated' (Site from DM).		
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: 26 Nov 2020 11:14:40

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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

Generated On: 26 Nov 2020 11:14:40

[Height](#)

Audit	User	Time (GMT)
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) (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.'	(b) (4), (b) (6)	15 Sep 2020 13:53:32
answered with 'updated' (Site from DM).		
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: 26 Nov 2020 11:14:40

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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 (1)

Generated On: 26 Nov 2020 11:14:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '10:15'	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '18 Aug 2020 10:15'	System	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '097.7' F	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

[Route of measurement](#)

Audit	User	Time (GMT)
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

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:46
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:46
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 13:29:46
User entered '15' 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: 26 Nov 2020 11:14:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:46
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:29:46
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Height

Audit	User	Time (GMT)
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) (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.'	(b) (4), (b) (6)	15 Sep 2020 13:53:32
answered with 'updated' (Site from DM).		
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: 26 Nov 2020 11:14:40

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.6' F	(b) (4), (b) (6)	19 Aug 2020 13:29:13

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:40

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	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: 26 Nov 2020 11:14:40

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:30:29
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:30:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 13:30:29
User entered '14' 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: 26 Nov 2020 11:14:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:30:29
Query 'Data is required. Please provide.' answered by System data change (Site from 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

US3752129

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:30:29
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 13:30:29
User entered '74' 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: 26 Nov 2020 11:14:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was the physical examination performed?

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:14:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:14:40

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(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: 26 Nov 2020 11:14:40

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'per CDM: please select yes or no for this field' (Site from DM).	(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: 26 Nov 2020 11:14:40

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 13:33:22

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '11:15'	(b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:15'	System	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 16:19:23

US3752129

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:33:56

US3752129

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:33:56

US3752129

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:50'	(b) (4), (b) (6)	19 Aug 2020 13:33:56

US3752129

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:40

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '10:46'	(b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 13:34:35

US3752129

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 13:34:44

US3752129

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 13:34:44

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	18 Aug 2020 16:44:58
User entered 'Yes (Y)'	System	18 Aug 2020 16:44:58

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	18 Aug 2020 16:44:58
User entered '98.6'	System	18 Aug 2020 16:44:58

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Aug 2020 16:44:58
User entered '18 Aug 2020 11:44'	System	18 Aug 2020 16:44:58

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	18 Aug 2020 22:55:50
User entered 'Yes (Y)'	System	18 Aug 2020 22:55:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	18 Aug 2020 22:55:50
User entered '98.0'	System	18 Aug 2020 22:55:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	18 Aug 2020 22:55:50
User entered 'Yes (Y)'	System	18 Aug 2020 22:55:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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
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).	(b) (4), (b) (6)	23 Aug 2020 02:46:48
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Aug 2020 22:55:50
User entered '18 Aug 2020 17:55'	System	18 Aug 2020 22:55:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:23:14
User entered '97.0'	System	20 Aug 2020 01:23:14

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:03:18
User entered 'Yes (Y)'	System	20 Aug 2020 23:03:18

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:03:18
User entered '97.3'	System	20 Aug 2020 23:03:18

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:03:18
User entered '20 Aug 2020 18:03'	System	20 Aug 2020 23:03:18

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:27:34
User entered 'Yes (Y)'	System	21 Aug 2020 21:27:34

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:27:34
User entered '98.0'	System	21 Aug 2020 21:27:34

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:27:34
User entered 'No (N)'	System	21 Aug 2020 21:27:34

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:27:34
User entered '21 Aug 2020 16:27'	System	21 Aug 2020 21:27:34

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:38:50
User entered 'Yes (Y)'	System	22 Aug 2020 20:38:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:38:50
User entered '97.7'	System	22 Aug 2020 20:38:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:38:50
User entered 'No (N)'	System	22 Aug 2020 20:38:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:38:50
User entered '22 Aug 2020 15:38'	System	22 Aug 2020 20:38:50

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:27:48
User entered 'Yes (Y)'	System	23 Aug 2020 17:27:48

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:27:48
User entered '97.7'	System	23 Aug 2020 17:27:48

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:56:13
User entered 'Yes (Y)'	System	24 Aug 2020 18:56:13

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:56:13
User entered '98.0'	System	24 Aug 2020 18:56:13

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:56:13
User entered '24 Aug 2020 13:56'	System	24 Aug 2020 18:56:13

US3752129

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	18 Aug 2020 22:56:38
User entered 'None (1)'	System	18 Aug 2020 22:56:38

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	18 Aug 2020 22:56:38
User entered '18 Aug 2020 17:56'	System	18 Aug 2020 22:56:38

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:23:57
User entered '19 Aug 2020 20:23'	System	20 Aug 2020 01:23:57

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:03:41
User entered '20 Aug 2020 18:03'	System	20 Aug 2020 23:03:41

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:27:49
User entered 'None (1)'	System	21 Aug 2020 21:27:49

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:27:49
User entered '21 Aug 2020 16:27'	System	21 Aug 2020 21:27:49

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:11
User entered 'No (N)'	System	22 Aug 2020 20:39:11

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:11
User entered 'No (N)'	System	22 Aug 2020 20:39:11

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:40

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:11
User entered 'None (1)'	System	22 Aug 2020 20:39:11

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:11
User entered '22 Aug 2020 15:39'	System	22 Aug 2020 20:39:11

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:04
User entered 'No (N)'	System	23 Aug 2020 17:28:04

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:04
User entered 'No (N)'	System	23 Aug 2020 17:28:04

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:04
User entered '23 Aug 2020 12:28'	System	23 Aug 2020 17:28:04

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:56:24
User entered 'None (1)'	System	24 Aug 2020 18:56:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:56:24
User entered 'No (N)'	System	24 Aug 2020 18:56:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:56:24
User entered 'No (N)'	System	24 Aug 2020 18:56:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:56:24
User entered 'None (1)'	System	24 Aug 2020 18:56:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 18:56:24
User entered '24 Aug 2020 13:56'	System	24 Aug 2020 18:56:24

US3752129

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	18 Aug 2020 16:45:51
User entered '18 Aug 2020 11:45'	System	18 Aug 2020 16:45:51

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:24:13
User entered 'None (0)'	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:24:13
User entered 'None (0)'	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:24:13
User entered 'None (0)'	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:24:13
User entered 'None (0)'	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:24:13
User entered 'None (0)'	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:24:13
User entered 'None (0)'	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:24:13
User entered 'No (N)'	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 01:24:13
User entered '19 Aug 2020 20:24'	System	20 Aug 2020 01:24:13

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:04:10
User entered 'None (0)'	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:04:10
User entered 'None (0)'	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:04:10
User entered 'None (0)'	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:04:10
User entered 'None (0)'	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:04:10
User entered 'None (0)'	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:04:10
User entered 'None (0)'	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:04:10
User entered 'No (N)'	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 23:04:10
User entered '20 Aug 2020 18:04'	System	20 Aug 2020 23:04:10

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:28:08
User entered 'None (0)'	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:28:08
User entered 'None (0)'	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:28:08
User entered 'None (0)'	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:28:08
User entered 'None (0)'	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:28:08
User entered 'None (0)'	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:28:08
User entered 'None (0)'	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:28:08
User entered 'No (N)'	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 21:28:08
User entered '21 Aug 2020 16:28'	System	21 Aug 2020 21:28:08

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:28
User entered 'None (0)'	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:28
User entered 'None (0)'	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:28
User entered 'None (0)'	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:28
User entered 'None (0)'	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:28
User entered 'None (0)'	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:28
User entered 'None (0)'	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 20:39:28
User entered '22 Aug 2020 15:39'	System	22 Aug 2020 20:39:28

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:20
User entered 'None (0)'	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:20
User entered 'None (0)'	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:20
User entered 'None (0)'	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:20
User entered 'None (0)'	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:20
User entered 'None (0)'	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:20
User entered 'None (0)'	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:20
User entered 'No (N)'	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 17:28:20
User entered '23 Aug 2020 12:28'	System	23 Aug 2020 17:28:20

US3752129

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:27:04

US3752129

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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).	System	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).	System	23 Sep 2020 20:08:32
User entered '26 Aug 2020' reason for change: Data Entry Error	Amanda Horn (b) (4) (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).	System	22 Sep 2020 18:27:04
User entered '9 Sep 2020'	(b) (4), (b) (6) (b) (4)	22 Sep 2020 18:27:04

US3752129

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 18:27:04

US3752129

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:27:04

US3752129

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 13:54:21

US3752129

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 13:54:21

US3752129

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:25:53

US3752129

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:25:53

US3752129

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 18:25:53

US3752129

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:25:53

US3752129

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 13:54:28

US3752129

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 13:54:28

US3752129

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 13:54:37

US3752129

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 13:54:37

US3752129

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 13:55:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 13:55:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 13:55:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	21 Sep 2020 13:55:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '08:20'	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:14:40

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:31
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:31
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:31
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:31
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:05:31
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:40

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:05:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(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: 26 Nov 2020 11:14:40

[If Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Pulse units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).		21 Sep 2020 18:06:53
User entered '14' 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: 26 Nov 2020 11:14:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 18:06:53
Query 'Data is required. Please provide.' answered by System data change (Site from 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: 26 Nov 2020 11:14:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:07:04

US3752129

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:07:04

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Date of test \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:07:27

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '08:51'	(b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:14:40

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 13:56:09

US3752129

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:08:07

US3752129

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 18:08:07

US3752129

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '08:40'	(b) (4), (b) (6)	21 Sep 2020 18:08:07

US3752129

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '08:38'	(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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 18:08:21

US3752129

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 18:08:43

US3752129

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 18:08:43

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:23:29
User entered '98.0'	System	21 Sep 2020 14:23:29

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:23:29
User entered '21 Sep 2020 09:23'	System	21 Sep 2020 14:23:29

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Sep 2020 22:05:26
User entered 'Yes (Y)'	System	21 Sep 2020 22:05:26

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Sep 2020 22:05:26
User entered '97.9'	System	21 Sep 2020 22:05:26

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	21 Sep 2020 22:05:26
User entered 'No (N)'	System	21 Sep 2020 22:05:26

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Sep 2020 22:05:26
User entered '21 Sep 2020 17:05'	System	21 Sep 2020 22:05:26

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:01:51
User entered '98.0'	System	22 Sep 2020 17:01:51

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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). 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 '1'	System	22 Sep 2020 17:01:51
	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: 26 Nov 2020 11:14:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
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 '0'	System	22 Sep 2020 17:01:51

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:01:51
User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:01:51

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:39:17
User entered '98.6'	System	24 Sep 2020 17:39:17

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:39:17
User entered '24 Sep 2020 12:39'	System	24 Sep 2020 17:39:17

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:19
User entered 'Yes (Y)'	System	25 Sep 2020 19:19:19

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:19
User entered '96.3'	System	25 Sep 2020 19:19:19

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:19
User entered 'No (N)'	System	25 Sep 2020 19:19:19

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:19
User entered '25 Sep 2020 14:19'	System	25 Sep 2020 19:19:19

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:06
User entered 'Yes (Y)'	System	26 Sep 2020 17:13:06

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:06
User entered '97.6'	System	26 Sep 2020 17:13:06

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:06
User entered '26 Sep 2020 12:13'	System	26 Sep 2020 17:13:06

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:23
User entered 'Yes (Y)'	System	27 Sep 2020 17:11:23

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:23
User entered '97.6'	System	27 Sep 2020 17:11:23

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:23
User entered 'No (N)'	System	27 Sep 2020 17:11:23

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:23
User entered '27 Sep 2020 12:11'	System	27 Sep 2020 17:11:23

US3752129

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:23:47
User entered 'None (1)'	System	21 Sep 2020 14:23:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:23:47
User entered 'No (N)'	System	21 Sep 2020 14:23:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:23:47
User entered 'No (N)'	System	21 Sep 2020 14:23:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:23:47
User entered 'None (1)'	System	21 Sep 2020 14:23:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:23:47
User entered '21 Sep 2020 09:23'	System	21 Sep 2020 14:23:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:02:30
User entered 'No (N)'	System	22 Sep 2020 17:02:30

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:02:30
User entered 'No (N)'	System	22 Sep 2020 17:02:30

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:02:30
User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:02:30

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	23 Sep 2020 17:07:16
User entered 'No (N)'	System	23 Sep 2020 17:07:16

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	23 Sep 2020 17:07:16
User entered 'No (N)'	System	23 Sep 2020 17:07:16

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 17:07:16
User entered '23 Sep 2020 12:03'	System	23 Sep 2020 17:07:16

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:33
User entered '25 Sep 2020 14:19'	System	25 Sep 2020 19:19:33

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:13
User entered 'No (N)'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:13
User entered 'No (N)'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:40

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

Please select one response below

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:13
User entered 'None (1)'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:13
User entered '26 Sep 2020 12:13'	System	26 Sep 2020 17:13:13

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:34
User entered 'No (N)'	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:34
User entered 'No (N)'	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:40

[Please record](#) - **UNDERARM GLAND SWELLING OR TENDERNESS.**

[Please select one response below](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:34
User entered 'None (1)'	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:34
User entered '27 Sep 2020 12:11'	System	27 Sep 2020 17:11:34

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:25:27
User entered 'None (0)'	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:25:27
User entered 'None (0)'	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:25:27
User entered 'None (0)'	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:25:27
User entered 'None (0)'	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:25:27
User entered 'None (0)'	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:25:27
User entered 'None (0)'	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:25:27
User entered 'No (N)'	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Sep 2020 14:25:27
User entered '21 Sep 2020 09:24'	System	21 Sep 2020 14:25:27

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	21 Sep 2020 22:05:55
User entered 'None (0)'	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Sep 2020 22:05:55
User entered 'None (0)'	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Sep 2020 22:05:55
User entered 'None (0)'	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	21 Sep 2020 22:05:55
User entered 'None (0)'	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	21 Sep 2020 22:05:55
User entered 'No (N)'	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Sep 2020 22:05:55
User entered '21 Sep 2020 17:05'	System	21 Sep 2020 22:05:55

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:03:25
User entered 'None (0)'	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:03:25
User entered 'None (0)'	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:03:25
User entered 'None (0)'	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:03:25
User entered 'None (0)'	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:03:25
User entered 'None (0)'	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:03:25
User entered 'None (0)'	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:03:25
User entered 'No (N)'	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	22 Sep 2020 17:03:25
User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:03:25

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	23 Sep 2020 17:07:32
User entered 'None (0)'	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	23 Sep 2020 17:07:32
User entered 'None (0)'	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	23 Sep 2020 17:07:32
User entered 'None (0)'	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	23 Sep 2020 17:07:32
User entered 'None (0)'	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	23 Sep 2020 17:07:32
User entered 'None (0)'	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	23 Sep 2020 17:07:32
User entered 'None (0)'	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 17:07:32
User entered '23 Sep 2020 12:03'	System	23 Sep 2020 17:07:32

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:39:45
User entered 'None (0)'	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:39:45
User entered 'None (0)'	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:39:45
User entered 'None (0)'	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:39:45
User entered 'No (N)'	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	24 Sep 2020 17:39:45
User entered '24 Sep 2020 12:39'	System	24 Sep 2020 17:39:45

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:51
User entered 'None (0)'	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:51
User entered 'None (0)'	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:51
User entered 'None (0)'	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:51
User entered 'None (0)'	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:51
User entered 'None (0)'	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:51
User entered 'None (0)'	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:51
User entered 'No (N)'	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 19:19:51
User entered '25 Sep 2020 14:19'	System	25 Sep 2020 19:19:51

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:28
User entered 'None (0)'	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:28
User entered 'None (0)'	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:28
User entered 'None (0)'	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:28
User entered 'None (0)'	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:28
User entered 'None (0)'	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:28
User entered 'None (0)'	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:28
User entered 'No (N)'	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	26 Sep 2020 17:13:28
User entered '26 Sep 2020 12:13'	System	26 Sep 2020 17:13:28

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

HEADACHE

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:50
User entered 'None (0)'	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:40

FATIGUE

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:50
User entered 'None (0)'	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:50
User entered 'None (0)'	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:50
User entered 'None (0)'	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:50
User entered 'None (0)'	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:40

CHILLS

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:50
User entered 'None (0)'	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 17:11:50
User entered '27 Sep 2020 12:11'	System	27 Sep 2020 17:11:50

US3752129

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:02:38
User entered '28 Sep 2020 12:02'	System	28 Sep 2020 17:02:38

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Please record - PAIN AT INJECTION SITE.](#)

[Please select one response below](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:00:47
User entered '29 Sep 2020 12:00'	System	29 Sep 2020 17:00:47

US3752129

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:02:43
User entered 'No (N)'	System	28 Sep 2020 17:02:43

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 17:02:43
User entered '28 Sep 2020 12:02'	System	28 Sep 2020 17:02:43

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 17:00:54
User entered '29 Sep 2020 12:00'	System	29 Sep 2020 17:00:54

US3752129

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:14:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 17:11:34

US3752129

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:54:24

US3752129

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 12:54:24

US3752129

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:54:40

US3752129

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 12:54:40

US3752129

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Oct 2020 12:54:40

US3752129

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 12:54:40

US3752129

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	07 Oct 2020 22:46:39

US3752129

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 22:46:39

US3752129

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 18:24:51

US3752129

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 18:24:51

US3752129

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 18:24:51

US3752129

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 18:24:51

US3752129

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 21:00:32

US3752129

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 21:00:32

US3752129

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 21:00:48

US3752129

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '26 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 21:00:48

US3752129

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Oct 2020 21:00:48

US3752129

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:14:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	27 Oct 2020 21:00:48

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '08:28'	(b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	(b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	(b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	(b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:14:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 21:01:25

US3752129

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 21:01:35

US3752129

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:14:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 21:01:35

US3752129

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 21:02:20

US3752129

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '26 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 21:02:20

US3752129

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '08:29'	(b) (4), (b) (6)	27 Oct 2020 21:02:20

US3752129

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 21:02:24

US3752129

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 21:02:24

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[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 (DC19B691-B2D6-4B8B-9278-7535E1CA3E65)', Time: '2020-10-18T15:30:23', User OID: 'PatientReportedOutcome (US3752129)', ODM File OID: 'adffca57-4ed1-4d52-85d1-c1e2724c9bea' User entered 'Yes (Y)'	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: 26 Nov 2020 11:14:40

[Have you been exposed to someone with 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 (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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

[Date and time of submission](#)

Audit	User	Time (GMT)
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'	System	18 Oct 2020 20:30:39
User entered '18 Oct 2020 15:30:36'	System	18 Oct 2020 20:30:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[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 (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: 26 Nov 2020 11:14:40

Have you been exposed to someone with 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 (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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (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: 26 Nov 2020 11:14:40

[Date and time of submission](#)

Audit	User	Time (GMT)
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'	System	26 Oct 2020 14:21:39
User entered '26 Oct 2020 09:21:31'	System	26 Oct 2020 14:21:39

US3752129

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[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 (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: 26 Nov 2020 11:14:40

Have you been exposed to someone with 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 (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: 26 Nov 2020 11:14:40

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

[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 Oct 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: 26 Nov 2020 11:14:40

[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 Oct 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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

[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 Oct 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: 26 Nov 2020 11:14:40

[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 Oct 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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

[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 Oct 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: 26 Nov 2020 11:14:40

[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 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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

[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 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: 26 Nov 2020 11:14:40

[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 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: 26 Nov 2020 11:14:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:09:55
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 22:09:55

US3752129

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:14:40

[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 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: 26 Nov 2020 11:14:40

[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 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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:18:19

US3752129

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	(b) (4), (b) (6)	16 Nov 2020 18:18:19

US3752129

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Nov 2020 18:18:19

US3752129

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:14:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Nov 2020 18:18:19

US3752129

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Nov 2020 18:18:26

US3752129

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:14:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 18:18:26

US3752129

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:14:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Amanda Horn (b) (4)	13 Oct 2020 16:53:59
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 13:35:14

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Adverse event](#)

Audit	User	Time (GMT)
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
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
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

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:29
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:31
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:33
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:37
User entered '21 Sep 2020'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Oct 2020 16:54:56
User entered empty.	Amanda Horn (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Ongoing?](#)

Audit	User	Time (GMT)
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)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

End time (00:00-23:59)

Audit	User	Time (GMT)
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
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

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:44
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:51
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:55
User entered '0'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:57
User entered '0'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:00
User entered '0'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:03
User entered empty.	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:06
User entered empty.	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:08
User entered empty.	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:09
User entered empty.	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:11
User entered '0'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:13
User entered '0'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:15
User entered '0'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

None

Audit	User	Time (GMT)
DataPoint Un-verified.	Amanda Horn (b) (4)	18 Nov 2020 15:55:16
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Amanda Horn (b) (4)	18 Nov 2020 15:55:16
DataPoint Verified.	(b) (4)	
	(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)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
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), (b) (6)	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)	
	Amanda Horn (b) (4)	18 Nov 2020 15:55:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	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
	(b) (4)	

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:08:21
User entered '0'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:08:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:08:25
User entered empty.	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:08:28
User entered empty.	Amanda Horn (b) (4) (b) (4)	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:14:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 16:54:56

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:43:06
Reviewed for Safety.	(b) (4), (b) (6)	10 Nov 2020 15:39:24
User entered 'USA-US113-2020-mRNA-1273-P301000010'	System	10 Nov 2020 15:39:19
User entered 'New'	(b) (4), (b) (6)	10 Nov 2020 15:39:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating the event term to the condition for which the surgery was performed.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:06:05
User opened query 'PV Query: Please consider updating the event term to the condition for which the surgery was performed.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:01:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy total - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:39:49
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 17:39:49
Data point term sent to Coder	System	17 Nov 2020 17:38:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
Data point term sent to Coder	System	17 Nov 2020 17:17:27
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:43:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy total - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 17:39:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 17:39:34
Data point term sent to Coder	System	09 Nov 2020 17:38:02
User entered 'TOTAL THYROIDECTOMY'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:43:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:43:15
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:43:16
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:43:20
User entered '02 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:43:22
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
User entered empty.	System	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:43:24
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 21:12:56
User closed query 'per source, end date should be 02OCT2020. Please correct date or clarify.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 21:12:55
Query 'per source, end date should be 02OCT2020. Please correct date or clarify.' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 16:56:39
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Nov 2020 16:56:32
User opened query 'per source, end date should be 02OCT2020. Please correct date or clarify.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 16:12:11
User entered '3 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:01
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
User entered empty.	System	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Severity](#)

Audit	User	Time (GMT)
Query 'PV Query: Since the subject was hospitalized for the event of total thyroidectomy, appropriate severity grade should be grade 4 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' answered with 'corrected' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 19:46:33
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 19:46:25
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:46:25
User opened query 'PV Query: Since the subject was hospitalized for the event of total thyroidectomy, appropriate severity grade should be grade 4 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:51:07
Query 'PV Query: Since the subject was hospitalized for the event of total thyroidectomy, appropriate severity grade should be grade 4 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:06:01
User opened query 'PV Query: Since the subject was hospitalized for the event of total thyroidectomy, appropriate severity grade should be grade 4 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:05:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Death](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:11
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:12
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:14
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:16
User entered '02 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:22
User entered '03 Oct 2020'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:24
User entered 'No (N)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:26
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:29
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:31
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:32
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:34
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:35
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with study drug for the events from none to not applicable.' answered with 'done' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 19:47:38
	(b) (4), (b) (6)	24 Nov 2020 19:47:29
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 19:47:29
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 for the events from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:50:31
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.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:05:56
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)	19 Nov 2020 22:05:07
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:38
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[None](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:42
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:44
User entered '1'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:45
User entered '0'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Outcome](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:48
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:51:18
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)	24 Nov 2020 16:50:17
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:05:53
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:05:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:44:53
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 17:38:15
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	09 Nov 2020 17:38:15
User entered 'SUBJECT ADMITTED TO HOSPITAL FOR THYROIDECTOMY. ADMISSION LESS THAN 24HOURS' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Nov 2020 17:38:15
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	09 Nov 2020 17:37:19
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
User entered '1'	System	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
User entered '1'	System	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:14:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	17 Nov 2020 17:38:24
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	17 Nov 2020 17:17:26
User entered '0'	System	09 Nov 2020 17:37:19

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:14:40

[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

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '01 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[Ongoing?](#)

Audit	User	Time (GMT)
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

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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). User entered empty.	(b) (4), (b) (6)	24 Nov 2020 16:51:54
	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	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: 26 Nov 2020 11:14:40

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	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: 26 Nov 2020 11:14:40

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
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

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 17:27:21
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Outcome](#)

Audit	User	Time (GMT)
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

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Narrative](#)

Audit	User	Time (GMT)
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

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 17:19:12

US3752129

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:14:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 17:27:21

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Adverse event](#)

Audit	User	Time (GMT)
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) (b) (4)	17 Nov 2020 17:31:00
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 17:31:00
Data point term sent to Coder	System	17 Nov 2020 17:29:37
User entered 'Hypocalcemia'	(b) (4), (b) (6) (b) (4)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Severity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 17:29:18

US3752129

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:14:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 17:29:18

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:14:40

[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

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:14:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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.	Coder Import (b) (4) (b) (4)	22 Aug 2020 19:34:18
Data point term sent to Coder	System	19 Aug 2020 13:38:09
User entered 'Mirena IUD'	(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: 26 Nov 2020 11:14:40

[Prophylaxis](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Frequency](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Route of administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Ongoing?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 16:16:13
User entered 'un UNK 2019' 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 15:46:52
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: 26 Nov 2020 11:14:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Name of Medication](#)

Audit	User	Time (GMT)
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) (b) (4)	27 Oct 2020 21:05:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 21:05:25
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: 26 Nov 2020 11:14:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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) (b) (4)	17 Nov 2020 17:10:29

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:14:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:14:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Post procedure infection prophylaxis'	(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: 26 Nov 2020 11:14:40

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(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: 26 Nov 2020 11:14:40

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(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: 26 Nov 2020 11:14:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:14:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(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: 26 Nov 2020 11:14:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:14:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(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: 26 Nov 2020 11:14:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(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: 26 Nov 2020 11:14:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(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: 26 Nov 2020 11:14:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:14:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(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: 26 Nov 2020 11:14:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:14:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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) (b) (4)	17 Nov 2020 17:11:55

US3752129

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:14:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:14:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypocalcemia'	(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: 26 Nov 2020 11:14:40

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Dose unit](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

If dose unit is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	(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: 26 Nov 2020 11:14:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(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: 26 Nov 2020 11:14:40

If route of administration is Other, specify

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(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: 26 Nov 2020 11:14:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(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: 26 Nov 2020 11:14:40

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(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: 26 Nov 2020 11:14:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[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: 26 Nov 2020 11:14:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 17:14:03

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:14:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Nov 2020 17:30:05

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:14:40

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Left thyroid fine needle aspiration with biopsy'	(b) (4), (b) (6)	17 Nov 2020 17:31:20

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:14:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Medical History (MH)'	(b) (4), (b) (6)	17 Nov 2020 17:31:20

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:14:40

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:31:20

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:14:40

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 17:31:58

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:14:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Total thyroidectomy'	(b) (4), (b) (6)	17 Nov 2020 17:31:58

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:14:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	17 Nov 2020 17:31:58

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:14:40

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:31:58

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:14:40

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	(b) (4), (b) (6)	17 Nov 2020 17:32:38

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:14:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Thyroid cancer ablation with I-131'	(b) (4), (b) (6)	17 Nov 2020 17:32:38

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:14:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	17 Nov 2020 17:32:38

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 26 Nov 2020 11:14:40

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Nov 2020 17:32:38

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:14:40

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	(b) (4), (b) (6)	17 Nov 2020 17:33:00

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:14:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Total body iodine scan'	(b) (4), (b) (6)	17 Nov 2020 17:33:00

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:14:40

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	17 Nov 2020 17:33:00

US3752129

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 26 Nov 2020 11:14:40

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(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: 26 Nov 2020 11:14:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Site Address: [City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Site Address: [City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

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)	17 Nov 2020 18:22:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:42:20
User entered '1'	(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: 26 Nov 2020 11:14:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:14:40

Site Address: [Street](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Site Address: [City](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Site Address: [State](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Investigator Country](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:14:40

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 entered '1'	(b) (4), (b) (6)	17 Nov 2020 18:22:48