

US3522529 (Prod: Henry Ford Health System)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:32:56

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US3522529

Form: Participant Creation

Generated On: 26 Nov 2020 09:32:56

[Participant ID](#)

US3522529

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

US3522529

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	44
Age Units	YEARS
Age (Derived)	44
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

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

Date of Informed Consent (<i>dd MMM yyyy</i>)	2 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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

US3522529

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:32:56

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3522529

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:32:56

Were any significant conditions reported?

Yes ☒

No ☐

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

Condition	MIGRAINES
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)	

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	2 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	12:17 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:17
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	169 lb
BMI (<i>xxx.x</i>)	28.18187 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	ND - Not Done
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)	

US3522529

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

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.

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:32:56

Date of assessment (*dd MMM yyyy*) 2 SEP 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

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	2 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☒
	No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐
	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐
	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐
	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐
	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐
	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐
	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐
	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐
	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐
	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐
	No ☒
Other	Yes ☐
	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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

US3522529

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:56

What was the date of randomization? (dd MMM yyyy) 02 SEP 2020

What was the participant's randomization number? 110955

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 ☒

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:56

Height	ND - Not Done
Weight	ND - Not Done

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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)	2 SEP 2020
Time of assessment (00:00-23:59)	12:17 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 12:17
Temperature (xxx.x)	98.8 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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)	2 SEP 2020
Time of assessment (00:00-23:59)	13:14 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 13:14
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3522529

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 SEP 2020

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

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

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) _____

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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)	2 SEP 2020
What was the treatment time? (00:00-23:59)	12:44 (24 HR)
Treatment Date and Time (derived)	2 SEP 2020 12:44
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

US3522529

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	2 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:30 (24 HR)
Collection date and time (derived)	2 SEP 2020 12:30

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:56

Collection date (<i>dd MMM yyyy</i>)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:36	2 SEP 2020 12:36
Nasopharyngeal Swab 2	No		

US3522529

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 13:11

PC Open Date & Time

02 SEP 2020 13:04

PC Close Date & Time

02 SEP 2020 15:34

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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 99.5 °F

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

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

PC Time Stamp	02 SEP 2020 16:30
PC Open Date & Time	02 SEP 2020 16:29
PC Close Date & Time	03 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 12:01

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

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	99.1 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	04 SEP 2020 12:01
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 13:32

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

06 SEP 2020 21:22

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

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	99.1 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	07 SEP 2020 20:02
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 14:51

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

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

02 SEP 2020 13:12

PC Open Date & Time

02 SEP 2020 13:04

PC Close Date & Time

02 SEP 2020 15:34

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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

02 SEP 2020 16:32

PC Open Date & Time

02 SEP 2020 16:29

PC Close Date & Time

03 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

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

03 SEP 2020 12:02

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

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

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

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

05 SEP 2020 13:32

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

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

06 SEP 2020 21:22

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

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

07 SEP 2020 20:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

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

08 SEP 2020 14:52

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 13:12
PC Open Date & Time	02 SEP 2020 13:04
PC Close Date & Time	02 SEP 2020 15:34

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 16:33
PC Open Date & Time	02 SEP 2020 16:29
PC Close Date & Time	03 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

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

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

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

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

Yes ☐	
PC Time stamp	05 SEP 2020 13:32
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

Yes ☐	
PC Time stamp	06 SEP 2020 21:23
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

Yes ☐	
PC Time stamp	07 SEP 2020 20:03
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

Yes ☐	
PC Time stamp	08 SEP 2020 14:52
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 10 SEP 2020 06:05

PC Open Date & Time 09 SEP 2020 12:00

PC Close Date & Time 10 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 10 SEP 2020 12:00

PC Open Date & Time 10 SEP 2020 12:00

PC Close Date & Time 11 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:11

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

10 SEP 2020 06:05

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

10 SEP 2020 12:00

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 SEP 2020 06:05
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 SEP 2020 12:00
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	12 SEP 2020 12:11
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3522529

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

EDIARY REVIEWED. PATIENT
REPORTS MILD PAIN AT
INJECTION SITE, HEADACHES,
MUSCLE/JOINT ACHES AND
FATIGUE THAT PEAKED ON
DAY 3 AND RETURNED ON
DAYS 6-8. SYMPTOMS
CONTROLLED WITH 800MG
OTC IBUPROFEN

US3522529

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522529

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK.

US3522529

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522529

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PATIENT CONTACTED, HAD
WENT TO HOSPITAL FOR
HERNIA AND ADMITTED FOR
LOW ELECTROLYTES ON
9/21/2020. PATIENT IS STILL
ADMITTED CURRENTLY.
PHYSICIAN CONTACTING

US3522529

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522529

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	12:22 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 12:22
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	12:55 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 12:55
Temperature (xxx.x)	97.5 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3522529

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	7 OCT 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	
Collection time	
Collection date and time (derived)	

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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) 7 OCT 2020

What was the treatment time? (00:00-23:59) 12:35 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 12:35

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

US3522529

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

7 OCT 2020

Collection time (*00:00-23:59*)

12:25 (24 HR)

Collection date and time (derived)

7 OCT 2020 12:25

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:56

Collection date (dd MMM yyyy)			7 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:30	7 OCT 2020 12:30
Nasopharyngeal Swab 2	No		

US3522529

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 07 OCT 2020 12:55

PC Close Date & Time 07 OCT 2020 15:25

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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 98.6 °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):

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

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

PC Time Stamp 07 OCT 2020 16:21

PC Open Date & Time 07 OCT 2020 16:20

PC Close Date & Time 08 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	99.7 °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):

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

PC Time Stamp	08 OCT 2020 12:00
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

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	99.0 °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	09 OCT 2020 14:57
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

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

10 OCT 2020 12:02

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	12 OCT 2020 09:42
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.4 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	12 OCT 2020 20:22
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp 14 OCT 2020 06:01

PC Open Date & Time 13 OCT 2020 12:00

PC Close Date & Time 14 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

07 OCT 2020 12:55

PC Close Date & Time

07 OCT 2020 15:25

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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

07 OCT 2020 16:22

PC Open Date & Time

07 OCT 2020 16:20

PC Close Date & Time

08 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 2

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 12:02

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

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

09 OCT 2020 14:57

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

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

10 OCT 2020 12:02

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 09:43

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

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

12 OCT 2020 20:22

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 06:01

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

07 OCT 2020 12:55

PC Close Date & Time

07 OCT 2020 15:25

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 16:22
PC Open Date & Time	07 OCT 2020 16:20
PC Close Date & Time	08 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

Yes ☐	
PC Time stamp	08 OCT 2020 12:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

Yes ☐	
PC Time stamp	09 OCT 2020 14:58
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

Yes ☐	
PC Time stamp	10 OCT 2020 12:02
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

Yes ☐	
PC Time stamp	12 OCT 2020 09:43
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

Yes ☐	
PC Time stamp	12 OCT 2020 20:23
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

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 ☒

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

Yes ☐	
PC Time stamp	14 OCT 2020 06:02
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 15 OCT 2020 06:40

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 15 OCT 2020 12:00

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 16 OCT 2020 12:06

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 15 OCT 2020 06:40

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 15 OCT 2020 12:00

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 16 OCT 2020 12:06

PC Open Date & Time 16 OCT 2020 12:00

PC Close Date & Time 17 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time Stamp 18 OCT 2020 00:00

PC Open Date & Time 17 OCT 2020 12:00

PC Close Date & Time 18 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 OCT 2020 06:40
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	15 OCT 2020 12:00
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	16 OCT 2020 12:07
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	18 OCT 2020 00:00
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3522529

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

SEE SOURCE. NO ONGOING OR
NEW AE REPORTED, NO NEW
ILLNESS OR HOSPITAL VISITS;
NO CHANGES IN HEALTH
STATUS, MEDICATIONS,
COVID-19 EXPOSURE OR
PREGNANCY RISK

US3522529

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522529

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

US3522529

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522529

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

NO ONGOING OR NEW AE
REPORTED, NO NEW ILLNESS
OR HOSPITAL VISITS; NO
CHANGES IN HEALTH STATUS,
MEDICATIONS, COVID-19
EXPOSURE OR PREGNANCY
RISK

US3522529

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522529

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	5 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	05 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	12:00 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 12:00
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522529

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 NOV 2020

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

US3522529

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	5 NOV 2020
Collection time (<i>00:00-23:59</i>)	12:10 (24 HR)
Collection date and time (derived)	5 NOV 2020 12:10

US3522529

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 NOV 2020 12:00:47
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 06:27:55
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Have 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	16 NOV 2020 06:04:12
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 FEB 2021 00:01

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09 FEB 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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

Date and time of submission

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12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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°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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 FEB 2021 00:01

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23 FEB 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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02 MAR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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09 MAR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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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02 APR 2021 00:01

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06 APR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

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17 AUG 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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°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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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25 JAN 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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01 FEB 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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08 FEB 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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15 FEB 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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22 FEB 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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01 MAR 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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08 MAR 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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15 MAR 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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19 APR 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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03 MAY 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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

Date and time of submission

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13 MAY 2022 00:01

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17 MAY 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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31 MAY 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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07 JUN 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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14 JUN 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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21 JUN 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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12 JUL 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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26 JUL 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 AUG 2022 00:01

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09 AUG 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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

Date and time of submission

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12 AUG 2022 00:01

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16 AUG 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 AUG 2022 00:01

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23 AUG 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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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30 AUG 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 SEP 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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

Date and time of submission

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13 SEP 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Please contact your study clinic immediately. Click below to confirm that you have read this 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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20 SEP 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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27 SEP 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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04 OCT 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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11 OCT 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

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18 OCT 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3522529

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

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

US3522529

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:56

Date of Contact	16 NOV 2020
Time of Contact	15:30
Date and Time of Contact (derived)	16 NOV 2020 15:30
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 ☐

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

Date of Visit	16 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☒ No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐ No ☒
Date of Test	16 NOV 2020
Type of Test Performed	Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐
Other, specify _____	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐ No ☒
If yes, provide lab information below	
Lab/ Institution Test Performed	_____
CLIA Certified?	Yes ☐ No ☐
COVID-19 Positive (CSA Programming Field Only)	0

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:32:56

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:32:56

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 NOV 2020
Day 5	Yes	20 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3522529

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	16 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	15:40 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 15:40
Height (<i>xxx.x</i>)	65 in
Weight (<i>xxx.x</i>)	175 lb
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	97 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522529

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3522529

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:32:56

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 NOV 2020

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

Was this visit performed?	Yes ☐
	No ☒

Visit date (dd MMM yyyy)	

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

Folder OID	SICKD28

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

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.

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:32:56

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☒

NA (COVID-19 Negative) ☐

Date of Collection

US3522529

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:32:56

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

AEID	USA-US131-2020-MRNA-1273-P30 1000006
Adverse event	DEGENERATIVE DISC DISEASE (MULTILEVEL)
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)	23 SEP 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)	21 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	23 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	368 of 2198

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

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	

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

WENT TO HOSPITAL 9/21 AFTER
PACKING AND MOVING
RECENTLY AND DEVELOPING
SEVERE LOW BACK PAIN. WAS
ADMITTED DUE TO
ELECTROLYTE
ABNORMALITIES IN LAB WITH
CALCIUM 5.1, K + 3.1, MG 1.1.
COVID 19 NP SWAB WAS GIVEN
ON INTAKE AND RESULTS
WERE NEGATIVE. NO
NAUSEA/VOMITING/DIARRHEA.
WAS GIVEN IV CORRECTION OF
MAGNESIUM/POTASSIUM/CALC
IUM. SENT HOME IN LATE
AFTERNOON ON SEP 23, 2020
WITH PREDNISONE DOSE,
ULTRAM AND ROBAXIN FOR
PAIN. (SEE CONCOM. MEDS).
FEELING BETTER, AND WANTS
TO STILL PARTICIPATE IN
TRIAL. DURING ADMITTANCE,
ENDOCRINOLOGIST
DETERMINED THAT THE
ELECTROLYTE IMBALANCE WAS
IN ACTUALITY A LAB ERROR
DUE TO RAPID
NORMALIZATION OF ALBUMIN
LEVELS IN 12 HOURS.

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

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

AEID	
Adverse event	HEADACHE DAY 8 AND DAY 9
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)	10 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)	11 SEP 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)	371 of 2198

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

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	PATIENT EXPERIENCED MILD HEADACHE DAY 8 AND DAY 9.
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)	

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

AEID	
Adverse event	MUSCLE ACHES ALL OVER BODY DAY 8
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	14 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	
v6.020 DTW (1102)	
373 of 2198	

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

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	True
Concomitant Medication	False
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	PATIENT STATES SHE IS STILL EXPERIENCING MILD MUSCLE ACHES ON DAY 8 AFTER INJECTION.
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)	

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

AEID	
Adverse event	FATIGUE
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)	15 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	16 NOV 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)	375 of 2198

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

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	True
Concomitant Medication	False
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	BROUGHT FOR ILLNESS VISIT. CLEARED UP IN A FEW DAYS AND WAS NEGATIVE FOR COVID-19 BY NP SWAB
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)	

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

AEID	
Adverse event	NASAL CONGESTION
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)	15 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	16 NOV 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)	377 of 2198

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

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	True
Concomitant Medication	False
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	BROUGHT FOR ILLNESS VISIT. CLEARED UP IN A FEW DAYS AND WAS NEGATIVE FOR COVID-19 BY NP SWAB
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)	

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

AEID	
Adverse event	SORE THROAT
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)	15 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	17 NOV 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)	379 of 2198

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

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	True
Concomitant Medication	False
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	BROUGHT FOR ILLNESS VISIT. CLEARED UP IN A FEW DAYS AND WAS NEGATIVE FOR COVID-19 BY NP SWAB
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)	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:32:56

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

Yes ☒

No ☐

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

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	MIGRAINES/HEADACHES/PAIN
Dose per administration	800
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 ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

	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)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
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 ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	ZOMIG-ZMT
Prophylaxis	Yes ☐ No ☒
Indication	MIGRAINES
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

	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)		
Start date completely unknown		True
Ongoing?		Yes ☒
		No ☐
If not Ongoing, End date (dd MMM yyyy)		
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 ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	MAGNESIUM SULFATE
Prophylaxis	Yes ☐ No ☒
Indication	PRESUMED ELECTROLYTE IMBALANCE
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☒ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

	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)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 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	☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	POTASSIUM CHLORIDE
Prophylaxis	Yes ☐ No ☒
Indication	PRESUMED ELECTROLYTE IMBALANCE
Dose per administration	20
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MEQ
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 ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

	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)	21 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	CALCIUM GLUCONATE
Prophylaxis	Yes ☐ No ☒
Indication	PRESUMED ELECTROLYTE IMBALANCE
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☒ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

	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)	21 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		21 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 ☐	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	HERNIATED DISC
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	23 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	27 SEP 2020
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 ☒

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	TRAMADOL
Prophylaxis	Yes ☐ No ☒
Indication	HERNIATED DISC
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☒ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	25 SEP 2020	
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	ROBAXIN
Prophylaxis	Yes ☐ No ☒
Indication	HERNIATED DISC
Dose per administration	UNKNOWN
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 ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		23 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		25 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 ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	MOTRIN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE, MUSCLE ACHE, JOINT PAIN
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 ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

	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)		07 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 12 OCT 2020		
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	☒

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	KDUR
Prophylaxis	Yes ☐ No ☒
Indication	PRESUMED ELECTROLYTE IMBALANCE
Dose per administration	40
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MEQ
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 ☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

	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)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		21 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	☐

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

Name of Medication	FLU VACCINE
Prophylaxis	Yes ☒
	No ☐
Indication	INFLUENZA
Dose per administration	UNK
Dose unit	mg ☐
	ug ☐
	mL ☐
	g ☐
	IU ☐
	tablet ☐
	capsule ☐
	puff ☐
	Other ☒
If dose unit is Other, specify	UNK
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 ☒

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

	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)		4 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		4 NOV 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	☐

US3522529

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:32:56

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3522529

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:32:56

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify

US3522529

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:32:56

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

US3522529

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:32:56

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 ☐

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

SAEID	USA-US131-2020-MRNA-1273-P301000006
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:32:56

SAEID	USA-US131-2020-MRNA-1273-P301000006
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/SEP/2020 21:48
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

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:32:56

SAEID	USA-US131-2020-MRNA-1273-P301000006
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	25/SEP/2020 14:45
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

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:32:56

SAEID	USA-US131-2020-MRNA-1273-P301000006
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	07/OCT/2020 13:01
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

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:32:56

SAEID	USA-US131-2020-MRNA-1273-P301000006
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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/OCT/2020 18:40
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.	True

Audit

US3522529 (Prod: Henry Ford Health System)

US3522529

Form: Participant Creation

Generated On: 26 Nov 2020 09:32:56

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3522529'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Sep 2020 16:05:28

US3522529

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:08:18

US3522529

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Sep 2020 16:05:30

US3522529

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Sep 2020 16:08:18

US3522529

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	02 Sep 2020 16:08:18

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered (b) (6) 1975'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 16:05:32

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Age](#)

Audit	User	Time (GMT)
User entered '44'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '44'	System	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:32:56

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:08:38

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2020'	System	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:09:10

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	02 Sep 2020 16:05:30

US3522529

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:32:56

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:32:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	16 Sep 2020 18:22:44
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:09:33

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 18:24:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 18:24:40
Data point term sent to Coder	System	16 Sep 2020 18:23:12
User entered 'Migraines'	Sharon Mathys (b) (4)	16 Sep 2020 18:23:00
	(b) (4)	

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:23:00

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:17'	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 12:17'	System	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '65' in	(b) (4), (b) (6)	02 Sep 2020 16:17:57
DataPoint set to visible.	System	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '169' lb	(b) (4), (b) (6)	02 Sep 2020 16:17:57
DataPoint set to visible.	System	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '28.18187'	System	02 Sep 2020 16:17:57
DataPoint set to visible.	System	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	02 Sep 2020 16:17:57
DataPoint set to visible.	System	02 Sep 2020 16:09:24

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 16:17:57

US3522529

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:09:39

US3522529

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:39

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	08 Sep 2020 18:43:56
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	02 Sep 2020 16:09:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:32:56

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	08 Sep 2020 18:43:56
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:32:56

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	08 Sep 2020 18:43:56
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 16:09:56

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 16:10:17

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

Other

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

Other

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:32:56

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:10:45

US3522529

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:11:03

US3522529

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '02 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 17:54:43
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:11:03

US3522529

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Sep 2020 16:11:03

US3522529

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	02 Sep 2020 16:11:03

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '02 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Sep 2020 16:05:38

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '110955'	RWS_ENDPOINT ENDPOINT (b) (4) 	02 Sep 2020 16:05:38

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:56

[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]	02 Sep 2020 16:05:38

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:11:14

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:11:14

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:11:14

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:11:14

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:56

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:11:14

US3522529

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4)	10 Nov 2020 17:54:34
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 04:54:17
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 04:54:16

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:56

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:56

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:56

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:56

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:17'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 12:17'	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '111'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:56

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:32:56

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 17:17:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 17:17:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 16:19:12
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '13:14' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 13:14'	System	02 Sep 2020 17:17:13
User entered empty.	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 17:17:13
User entered empty.	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 17:17:13
User entered empty.	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '116' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 17:17:13
User entered empty.	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Sep 2020 17:17:13
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 17:17:13
User entered empty.	System	02 Sep 2020 16:19:12

US3522529

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:11:38

US3522529

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:11:38

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Test performed](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Result](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:06:31
User entered 'No (N)' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	08 Sep 2020 17:51:27
Query 'Per CDM: Response is required at this field. Please consider to update else clarify.' answered with 'correct per ccg' (Site from DM).	Sharon Mathys (b) (4)	08 Sep 2020 13:48:46
User opened query 'Per CDM: Response is required at this field. Please consider to update else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 11:23:57
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 16:11:29

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:44'	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 12:44'	System	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 16:46:18

US3522529

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:42:36

US3522529

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:42:36

US3522529

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:30'	(b) (4), (b) (6)	02 Sep 2020 16:42:36

US3522529

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 12:30'	System	02 Sep 2020 16:42:36

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020'	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:56

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:36'	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 12:36'	System	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:56

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Sep 2020 14:31:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Sep 2020 14:31:37
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	09 Sep 2020 14:31:37
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 16:42:53
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 16:42:53

US3522529

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 16:46:02

US3522529

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 16:46:02

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:10:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6e79a261-695d-48c1-aeb0-0c700c5f15ad'	System	02 Sep 2020 17:11:07
User entered 'Yes (Y)'	System	02 Sep 2020 17:11:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:10:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6e79a261-695d-48c1-aeb0-0c700c5f15ad'	System	02 Sep 2020 17:11:07
User entered '98.1'	System	02 Sep 2020 17:11:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:11:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6e79a261-695d-48c1-aeb0-0c700c5f15ad'	System	02 Sep 2020 17:11:07
User entered 'No (N)'	System	02 Sep 2020 17:11:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:11:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6e79a261-695d-48c1-aeb0-0c700c5f15ad'	System	02 Sep 2020 17:11:07
User entered '02 Sep 2020 13:11'	System	02 Sep 2020 17:11:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:04'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 15:34'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:29:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3b09caf3-86c0-4e18-8e8c-9454d34e7010'	System	02 Sep 2020 20:30:48
User entered 'Yes (Y)'	System	02 Sep 2020 20:30:48

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:30:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3b09caf3-86c0-4e18-8e8c-9454d34e7010'	System	02 Sep 2020 20:30:48
User entered '99.5'	System	02 Sep 2020 20:30:48

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:30:42', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3b09caf3-86c0-4e18-8e8c-9454d34e7010'	System	02 Sep 2020 20:30:48
User entered 'No (N)'	System	02 Sep 2020 20:30:48

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:30:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3b09caf3-86c0-4e18-8e8c-9454d34e7010'	System	02 Sep 2020 20:30:48
User entered '02 Sep 2020 16:30'	System	02 Sep 2020 20:30:48

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 2'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:32', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd020da26-0f61-4cfe-9fd8-a23cff8c3a8a'	System	03 Sep 2020 16:03:20
User entered 'Yes (Y)'	System	03 Sep 2020 16:03:20

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd020da26-0f61-4cfe-9fd8-a23cff8c3a8a' User entered '98.7'	System	03 Sep 2020 16:03:20

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd020da26-0f61-4cfe-9fd8-a23cff8c3a8a'	System	03 Sep 2020 16:03:20
User entered 'No (N)'	System	03 Sep 2020 16:03:20

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'd020da26-0f61-4cfe-9fd8-a23cff8c3a8a'	System	03 Sep 2020 16:03:20
User entered '03 Sep 2020 12:01'	System	03 Sep 2020 16:03:20

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 3'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:00:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed'	System	04 Sep 2020 16:03:33
User entered 'Yes (Y)'	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:01:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed' User entered '99.1'	System	04 Sep 2020 16:03:33
	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:01:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed'	System	04 Sep 2020 16:03:33
User entered 'Yes (Y)'	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

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 'from safety call day 8, used ibuprophen for pain see line 1 in concom. meds' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 09:31:42
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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:01:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed'	Sharon Mathys (b) (4)	23 Sep 2020 16:51:46
User entered '1'	System	04 Sep 2020 16:03:33
	System	04 Sep 2020 16:03:33
	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:01:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed'	System	04 Sep 2020 16:03:33
User entered '0'	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:01:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'cbf8c7c4-3b2a-4694-ae35-f0cb207d80ed'	System	04 Sep 2020 16:03:33
User entered '04 Sep 2020 12:01'	System	04 Sep 2020 16:03:33

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 4'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:30:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a2575ca3-73d2-4312-b766-d1e72d65f102'	System	05 Sep 2020 17:32:07
User entered 'Yes (Y)'	System	05 Sep 2020 17:32:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:31:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a2575ca3-73d2-4312-b766-d1e72d65f102'	System	05 Sep 2020 17:32:07
User entered '99.1'	System	05 Sep 2020 17:32:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:31:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a2575ca3-73d2-4312-b766-d1e72d65f102'	System	05 Sep 2020 17:32:07
User entered 'No (N)'	System	05 Sep 2020 17:32:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:01', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a2575ca3-73d2-4312-b766-d1e72d65f102'	System	05 Sep 2020 17:32:07
User entered '05 Sep 2020 13:32'	System	05 Sep 2020 17:32:07

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 5'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3a1ec1f9-0ee0-4b1d-ad3a-f82c7f9dafaef'	System	07 Sep 2020 01:22:30
User entered 'Yes (Y)'	System	07 Sep 2020 01:22:30

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:23', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3a1ec1f9-0ee0-4b1d-ad3a-f82c7f9dafa'	System	07 Sep 2020 01:22:30
User entered '98.9'	System	07 Sep 2020 01:22:30

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3a1ec1f9-0ee0-4b1d-ad3a-f82c7f9dafa'	System	07 Sep 2020 01:22:30
User entered 'No (N)'	System	07 Sep 2020 01:22:30

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:28', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '3a1ec1f9-0ee0-4b1d-ad3a-f82c7f9dafaef'	System	07 Sep 2020 01:22:30
User entered '06 Sep 2020 21:22'	System	07 Sep 2020 01:22:30

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 6'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:00:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3'	System	08 Sep 2020 00:02:37
User entered 'Yes (Y)'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:22', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3'	System	08 Sep 2020 00:02:37
User entered '99.1'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3'	System	08 Sep 2020 00:02:37
User entered 'Yes (Y)'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

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 'from safety call day 8, used ibuprophen for pain see line 1 in concom. meds' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 09:31:53
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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3' User entered '1'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 16:51:58
	System	08 Sep 2020 00:02:37
	System	08 Sep 2020 00:02:37
	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3'	System	08 Sep 2020 00:02:37
User entered '0'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'bb45d10f-e66c-4254-9be5-03809a1055d3'	System	08 Sep 2020 00:02:37
User entered '07 Sep 2020 20:02'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 7'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a8a163f6-8554-4347-a980-ea1641c1356b'	System	08 Sep 2020 18:51:52
User entered 'Yes (Y)'	System	08 Sep 2020 18:51:52

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a8a163f6-8554-4347-a980-ea1641c1356b' User entered '98.8'	System	08 Sep 2020 18:51:52

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a8a163f6-8554-4347-a980-ea1641c1356b'	System	08 Sep 2020 18:51:52
User entered 'No (N)'	System	08 Sep 2020 18:51:52

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'a8a163f6-8554-4347-a980-ea1641c1356b' User entered '08 Sep 2020 14:51'	System	08 Sep 2020 18:51:52
	System	08 Sep 2020 18:51:52

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:11:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b062cff4-9a7e-4ab8-bca6-0eefab93392a'	System	02 Sep 2020 17:12:26
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 17:12:26

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b062cff4-9a7e-4ab8-bca6-0eefab93392a' User entered 'No (N)'	System	02 Sep 2020 17:12:26

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b062cff4-9a7e-4ab8-bca6-0eefab93392a' User entered 'No (N)'	System	02 Sep 2020 17:12:26

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:21', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b062cff4-9a7e-4ab8-bca6-0eefab93392a' User entered 'None (1)'	System	02 Sep 2020 17:12:26
	System	02 Sep 2020 17:12:26

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b062cff4-9a7e-4ab8-bca6-0eefab93392a' User entered '02 Sep 2020 13:12'	System	02 Sep 2020 17:12:26
	System	02 Sep 2020 17:12:26

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:04'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 15:34'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:31:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'aa62c5ef-32e0-4a3f-8a5f-652154a12e77'	System	02 Sep 2020 20:32:46
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 20:32:46

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:31:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'aa62c5ef-32e0-4a3f-8a5f-652154a12e77'	System	02 Sep 2020 20:32:46
User entered 'No (N)'	System	02 Sep 2020 20:32:46

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:31:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'aa62c5ef-32e0-4a3f-8a5f-652154a12e77'	System	02 Sep 2020 20:32:46
User entered 'No (N)'	System	02 Sep 2020 20:32:46

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:32:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'aa62c5ef-32e0-4a3f-8a5f-652154a12e77'	System	02 Sep 2020 20:32:46
User entered 'None (1)'	System	02 Sep 2020 20:32:46

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:32:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'aa62c5ef-32e0-4a3f-8a5f-652154a12e77'	System	02 Sep 2020 20:32:46
User entered '02 Sep 2020 16:32'	System	02 Sep 2020 20:32:46

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 2'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '181c699f-570c-43d6-9dcb-2eeb6dda27c6'	System	03 Sep 2020 16:03:53
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 16:03:53

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:01:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '181c699f-570c-43d6-9dcb-2eeb6dda27c6'	System	03 Sep 2020 16:03:53
User entered 'No (N)'	System	03 Sep 2020 16:03:53

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:04', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '181c699f-570c-43d6-9dcb-2eeb6dda27c6'	System	03 Sep 2020 16:03:53
User entered 'No (N)'	System	03 Sep 2020 16:03:53

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:07', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '181c699f-570c-43d6-9dcb-2eeb6dda27c6'	System	03 Sep 2020 16:03:53
User entered 'None (1)'	System	03 Sep 2020 16:03:53

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '181c699f-570c-43d6-9dcb-2eeb6dda27c6'	System	03 Sep 2020 16:03:53
User entered '03 Sep 2020 12:02'	System	03 Sep 2020 16:03:53

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 3'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:07', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c7be4e76-3d15-420d-a552-6e6d3ad62fbd'	System	04 Sep 2020 16:04:02
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	04 Sep 2020 16:04:02

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c7be4e76-3d15-420d-a552-6e6d3ad62fbd'	System	04 Sep 2020 16:04:02
User entered 'No (N)'	System	04 Sep 2020 16:04:02

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:11', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c7be4e76-3d15-420d-a552-6e6d3ad62fbd' User entered 'No (N)'	System	04 Sep 2020 16:04:02

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c7be4e76-3d15-420d-a552-6e6d3ad62fbd' User entered 'None (1)'	System	04 Sep 2020 16:04:02
	System	04 Sep 2020 16:04:02

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:17', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c7be4e76-3d15-420d-a552-6e6d3ad62fbd' User entered '04 Sep 2020 12:02'	System	04 Sep 2020 16:04:02
	System	04 Sep 2020 16:04:02

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 4'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:08', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '23679c07-1e53-4491-91c5-22e2583c7bb4'	System	05 Sep 2020 17:32:24
User entered 'None (1)'	System	05 Sep 2020 17:32:24

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:10', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '23679c07-1e53-4491-91c5-22e2583c7bb4'	System	05 Sep 2020 17:32:24
User entered 'No (N)'	System	05 Sep 2020 17:32:24

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:12', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '23679c07-1e53-4491-91c5-22e2583c7bb4'	System	05 Sep 2020 17:32:24
User entered 'No (N)'	System	05 Sep 2020 17:32:24

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '23679c07-1e53-4491-91c5-22e2583c7bb4'	System	05 Sep 2020 17:32:24
User entered 'None (1)'	System	05 Sep 2020 17:32:24

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '23679c07-1e53-4491-91c5-22e2583c7bb4'	System	05 Sep 2020 17:32:24
User entered '05 Sep 2020 13:32'	System	05 Sep 2020 17:32:24

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 5'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d1c316b-ca07-413b-bb92-7405ebbc5a3b'	System	07 Sep 2020 01:22:49
User entered 'None (1)'	System	07 Sep 2020 01:22:49

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d1c316b-ca07-413b-bb92-7405ebbc5a3b'	System	07 Sep 2020 01:22:49
User entered 'No (N)'	System	07 Sep 2020 01:22:49

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d1c316b-ca07-413b-bb92-7405ebbc5a3b'	System	07 Sep 2020 01:22:49
User entered 'No (N)'	System	07 Sep 2020 01:22:49

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d1c316b-ca07-413b-bb92-7405ebbc5a3b'	System	07 Sep 2020 01:22:49
User entered 'None (1)'	System	07 Sep 2020 01:22:49

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '4d1c316b-ca07-413b-bb92-7405ebbc5a3b'	System	07 Sep 2020 01:22:49
User entered '06 Sep 2020 21:22'	System	07 Sep 2020 01:22:49

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 6'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '286722c6-9374-40db-b4c1-4b1238803152'	System	08 Sep 2020 00:02:51
User entered 'None (1)'	System	08 Sep 2020 00:02:51

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '286722c6-9374-40db-b4c1-4b1238803152'	System	08 Sep 2020 00:02:51
User entered 'No (N)'	System	08 Sep 2020 00:02:51

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '286722c6-9374-40db-b4c1-4b1238803152'	System	08 Sep 2020 00:02:51
User entered 'No (N)'	System	08 Sep 2020 00:02:51

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '286722c6-9374-40db-b4c1-4b1238803152'	System	08 Sep 2020 00:02:51
User entered 'None (1)'	System	08 Sep 2020 00:02:51

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '286722c6-9374-40db-b4c1-4b1238803152'	System	08 Sep 2020 00:02:51
User entered '07 Sep 2020 20:02'	System	08 Sep 2020 00:02:51

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 7'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '37111e31-c6ba-4613-a6a5-7e02d77a18db' User entered 'None (1)'	System	08 Sep 2020 18:52:06
	System	08 Sep 2020 18:52:06

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:56', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '37111e31-c6ba-4613-a6a5-7e02d77a18db'	System	08 Sep 2020 18:52:06
User entered 'No (N)'	System	08 Sep 2020 18:52:06

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '37111e31-c6ba-4613-a6a5-7e02d77a18db' User entered 'No (N)'	System	08 Sep 2020 18:52:06

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:51:59', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '37111e31-c6ba-4613-a6a5-7e02d77a18db' User entered 'None (1)'	System	08 Sep 2020 18:52:06
	System	08 Sep 2020 18:52:06

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:01', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '37111e31-c6ba-4613-a6a5-7e02d77a18db' User entered '08 Sep 2020 14:52'	System	08 Sep 2020 18:52:06
	System	08 Sep 2020 18:52:06

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'No interference with activity (1)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'None (0)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'None (0)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'None (0)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:42', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'None (0)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'None (0)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered 'No (N)'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T13:12:49', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '45d85b88-49ec-4ffe-af58-11f034d79533'	System	02 Sep 2020 17:12:51
User entered '02 Sep 2020 13:12'	System	02 Sep 2020 17:12:51

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:04'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 15:34'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:32:49', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'None (0)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:32:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e'	System	02 Sep 2020 20:33:20
User entered 'No interference with activity (1)'	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:32:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'None (0)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:33:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'None (0)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:33:05', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'None (0)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:33:08', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'None (0)'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:33:11', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered 'No (N)'	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-02T16:33:17', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '08b5863a-7585-4c0d-a380-a29b6583957e' User entered '02 Sep 2020 16:33'	System	02 Sep 2020 20:33:20
	System	02 Sep 2020 20:33:20

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 16:29'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 2'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:17', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4'	System	03 Sep 2020 16:05:07
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:20', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4'	System	03 Sep 2020 16:05:07
User entered 'No interference with activity (1)'	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4'	System	03 Sep 2020 16:05:07
User entered 'None (0)'	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4' User entered 'None (0)'	System	03 Sep 2020 16:05:07
	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4'	System	03 Sep 2020 16:05:07
User entered 'None (0)'	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4'	System	03 Sep 2020 16:05:07
User entered 'None (0)'	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:02:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4' User entered 'No (N)'	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-03T12:03:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '33480d2c-48ae-4872-ba27-8fecc97770e4' User entered '03 Sep 2020 12:03'	System	03 Sep 2020 16:05:07
	System	03 Sep 2020 16:05:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 3'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e'	System	04 Sep 2020 16:04:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e'	System	04 Sep 2020 16:04:42
User entered 'Some interference with activity (2)'	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e'	System	04 Sep 2020 16:04:42
User entered 'Some interference with activity (2)'	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e'	System	04 Sep 2020 16:04:42
User entered 'Some interference with activity (2)'	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e'	System	04 Sep 2020 16:04:42
User entered 'None (0)'	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e'	System	04 Sep 2020 16:04:42
User entered 'No interference with activity (1)'	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e'	System	04 Sep 2020 16:04:42
User entered 'No (N)'	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-04T12:02:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6ab72d3f-044d-435f-96ee-10382dc2b11e'	System	04 Sep 2020 16:04:42
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 16:04:42

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 4'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a'	System	05 Sep 2020 17:32:43
User entered 'None (0)'	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a'	System	05 Sep 2020 17:32:43
User entered 'None (0)'	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a'	System	05 Sep 2020 17:32:43
User entered 'None (0)'	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a' User entered 'None (0)'	System	05 Sep 2020 17:32:43
	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a'	System	05 Sep 2020 17:32:43
User entered 'None (0)'	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a'	System	05 Sep 2020 17:32:43
User entered 'None (0)'	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a'	System	05 Sep 2020 17:32:43
User entered 'No (N)'	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-05T13:32:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '13d56418-7b2c-4472-8847-6a39a650cc7a' User entered '05 Sep 2020 13:32'	System	05 Sep 2020 17:32:43
	System	05 Sep 2020 17:32:43

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 5'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'None (0)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'None (0)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'None (0)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'None (0)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'None (0)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:22:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'None (0)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:23:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered 'No (N)'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-06T21:23:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '99156d18-63b4-4a64-825a-cf411b1bc767'	System	07 Sep 2020 01:23:07
User entered '06 Sep 2020 21:23'	System	07 Sep 2020 01:23:07

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 6'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf'	System	08 Sep 2020 00:03:21
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:02:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf'	System	08 Sep 2020 00:03:21
User entered 'Some interference with activity (2)'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:01', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf' User entered 'None (0)'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:07', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf' User entered 'None (0)'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf'	System	08 Sep 2020 00:03:21
User entered 'None (0)'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:11', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf'	System	08 Sep 2020 00:03:21
User entered 'None (0)'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf'	System	08 Sep 2020 00:03:21
User entered 'No (N)'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-07T20:03:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '470e657e-8ef9-47fd-ae09-1ed879dfcddf' User entered '07 Sep 2020 20:03'	System	08 Sep 2020 00:03:21
	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 7'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:10', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6'	System	08 Sep 2020 18:52:29
User entered 'No interference with activity (1)'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6'	System	08 Sep 2020 18:52:29
User entered 'No interference with activity (1)'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:16', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6'	System	08 Sep 2020 18:52:29
User entered 'None (0)'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6'	System	08 Sep 2020 18:52:29
User entered 'None (0)'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:20', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6'	System	08 Sep 2020 18:52:29
User entered 'None (0)'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:22', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6'	System	08 Sep 2020 18:52:29
User entered 'None (0)'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6'	System	08 Sep 2020 18:52:29
User entered 'No (N)'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-08T14:52:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2fe54e06-b94e-4c61-9aa7-22021c004ab6'	System	08 Sep 2020 18:52:29
User entered '08 Sep 2020 14:52'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 00:03:21
User entered 'Day 8'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c5e5fade-8cf3-4201-8452-9e1c5f09205d'	System	10 Sep 2020 10:05:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c5e5fade-8cf3-4201-8452-9e1c5f09205d'	System	10 Sep 2020 10:05:37
User entered '10 Sep 2020 06:05'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:52:29
User entered 'Day 9'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fa357290-0937-449c-ad0e-0d84ebfb44de'	System	10 Sep 2020 16:00:47
User entered 'No interference with activity (1)'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fa357290-0937-449c-ad0e-0d84ebfb44de'	System	10 Sep 2020 16:00:47
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 10:05:37
User entered 'Day 10'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 16:00:47
User entered 'Day 11'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:11:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e191cd57-23a8-4bc2-94be-2b257f0ef8f9'	System	12 Sep 2020 16:16:45
User entered 'None (0)'	System	12 Sep 2020 16:16:45

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:11:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e191cd57-23a8-4bc2-94be-2b257f0ef8f9'	System	12 Sep 2020 16:16:45
User entered '12 Sep 2020 12:11'	System	12 Sep 2020 16:16:45

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 00:03:21
User entered 'Day 8'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '57724233-6a8e-4787-bc66-49de60b46f29'	System	10 Sep 2020 10:05:45
User entered 'No interference with activity (1)'	System	10 Sep 2020 10:05:45

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '57724233-6a8e-4787-bc66-49de60b46f29'	System	10 Sep 2020 10:05:45
User entered '10 Sep 2020 06:05'	System	10 Sep 2020 10:05:45

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 00:03:21

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:52:29
User entered 'Day 9'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ddaf3dda-0538-49f4-ae05-04aec01823fe'	System	10 Sep 2020 16:01:17
User entered 'No interference with activity (1)'	System	10 Sep 2020 16:01:17

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ddaf3dda-0538-49f4-ae05-04aec01823fe' User entered '10 Sep 2020 12:00'	System	10 Sep 2020 16:01:17
	System	10 Sep 2020 16:01:17

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 10:05:45
User entered 'Day 10'	System	10 Sep 2020 10:05:45

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 10:05:45

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 10:05:45

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 16:01:17
User entered 'Day 11'	System	10 Sep 2020 16:01:17

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:11:56', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2633ffbe-fff5-4433-9624-7052d175e440'	System	12 Sep 2020 16:16:50
User entered 'None (0)'	System	12 Sep 2020 16:16:50

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:12:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '2633ffbe-fff5-4433-9624-7052d175e440'	System	12 Sep 2020 16:16:50
User entered '12 Sep 2020 12:12'	System	12 Sep 2020 16:16:50

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:01:17

US3522529

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:01:17

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 00:02:37
User entered 'Day 8'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b699eac5-bd02-4a83-9443-bff29203a65b'	System	10 Sep 2020 10:05:56
User entered 'No (N)'	System	10 Sep 2020 10:05:56

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T06:05:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b699eac5-bd02-4a83-9443-bff29203a65b'	System	10 Sep 2020 10:05:56
User entered '10 Sep 2020 06:05'	System	10 Sep 2020 10:05:56

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 00:02:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 18:52:29
User entered 'Day 9'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '137fc4a1-9bfe-4f27-876c-c70e9cdc5748'	System	10 Sep 2020 16:01:41
User entered 'No (N)'	System	10 Sep 2020 16:01:41

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-10T12:00:49', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '137fc4a1-9bfe-4f27-876c-c70e9cdc5748'	System	10 Sep 2020 16:01:41
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 16:01:41

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 18:52:29

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 10:05:37
User entered 'Day 10'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 10:05:37

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 16:00:47
User entered 'Day 11'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:11:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ce0d7c4f-f29a-44bc-b8f6-58e7af426f2f'	System	12 Sep 2020 16:16:48
User entered 'No (N)'	System	12 Sep 2020 16:16:48

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-09-12T12:11:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ce0d7c4f-f29a-44bc-b8f6-58e7af426f2f' User entered '12 Sep 2020 12:11'	System	12 Sep 2020 16:16:48
	System	12 Sep 2020 16:16:48

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 16:00:47

US3522529

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 16:00:47

US3522529

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 19:07:10

US3522529

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

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).	(b) (4), (b) (6)	16 Sep 2020 05:04:25
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 with 'Contact attempted twice prior to patient returning call. ' (Site from System).	Alandra White (b) (4)	15 Sep 2020 13:06:13
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	15 Sep 2020 13:05:31
User entered '15 Sep 2020' reason for change: New Information	Alandra White (b) (4)	15 Sep 2020 13:05:31
User entered '10 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4)	10 Sep 2020 22:25:40
User entered '9 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 19:07:10

US3522529

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:05:31
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6) (b) (4)	09 Sep 2020 19:07:10

US3522529

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'EDIARY REVIEWED. PATIENT REPORTS MILD PAIN AT INJECTION SITE, HEADACHES, MUSCLE/JOINT ACHES AND FATIGUE THAT PEAKED ON DAY 3 AND RETURNED ON DAYS 6-8. SYMPTOMS CONTROLLED WITH 800MG OTC IBUPROFEN' reason for change: New Information	Alandra White (b) (4)	15 Sep 2020 13:06:47
User entered 'eDiary reviewed. Patient reports mild pain at injection site, headaches, muscle/joint aches and fatigue that peaked on day 3 and returned mildly on days 6-8. Symptoms controlled with 800mg OTC ibuprofen PRN and no medical intervention.' (non-conformant).	Alandra White (b) (4)	15 Sep 2020 13:05:31
User entered '1ST ATTEMPT ON 09 SEP 2020; SECOND ATTEMPT 10 SEP 2020, left a voicemail' reason for change: New Information	Yaman Ahmed (b) (4)	10 Sep 2020 22:26:20
User entered '1st attempt on 09 Sep 2020; second attempt 10 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4)	10 Sep 2020 22:25:40
User entered 'Voicemail full'	(b) (4), (b) (6)	09 Sep 2020 19:07:10

US3522529

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:06:53

US3522529

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 13:06:53

US3522529

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 18:32:53

US3522529

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 18:32:53

US3522529

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 18:32:53

US3522529

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4), (b) (6)	16 Sep 2020 18:32:53

US3522529

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 18:32:57

US3522529

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 18:32:57

US3522529

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 14:59:09

US3522529

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 14:59:09

US3522529

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 14:59:09

US3522529

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Patient contacted, had went to hospital for hernia and admitted for low electrolytes on 9/21/2020. Patient is still admitted currently. physician contacting'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 14:59:09

US3522529

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:41:41

US3522529

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:41:41

US3522529

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:44:02

US3522529

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 16:44:02

US3522529

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Oct 2020 16:44:02

US3522529

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	07 Oct 2020 16:44:02

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:22'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '7 Oct 2020 12:22'	System	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '118'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:32:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 16:46:01

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User closed query 'Per CDM: The treatment time on the Exposure CRF is 12:35 and the Vital Signs Post Dose Time of Assessment is 12:55 which has 20 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:07:00
Query 'Per CDM: The treatment time on the Exposure CRF is 12:35 and the Vital Signs Post Dose Time of Assessment is 12:55 which has 20 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' answered with 'Deviation, staff retrained' (Site from DM).	Sharon Mathys (b) (4)	20 Oct 2020 14:13:12
User opened query 'Per CDM: The treatment time on the Exposure CRF is 12:35 and the Vital Signs Post Dose Time of Assessment is 12:55 which has 20 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. "Please clarify" the post dosing time of assessment and update as needed.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 04:49:18
User entered '12:55'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '7 Oct 2020 12:55'	System	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '97.5' F reason for change: Data Entry Error	Alandra White (b) (4)	20 Oct 2020 18:27:04
User entered '99.5' F	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'TEMPORAL'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '120'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '77'	(b) (4), (b) (6)	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:32:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Oct 2020 16:55:14

US3522529

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:46:10

US3522529

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 16:46:10

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:46:24

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:35'	(b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '7 Oct 2020 12:35'	System	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 16:42:03

US3522529

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3522529

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3522529

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:25'	(b) (4), (b) (6)	07 Oct 2020 16:46:46

US3522529

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '7 Oct 2020 12:25'	System	07 Oct 2020 16:46:46

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:32:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:56

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:30'	(b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '7 Oct 2020 12:30'	System	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:56

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:47:06

US3522529

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 16:47:13

US3522529

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:47:13

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:55'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 15:25'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:20:32', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062'	System	07 Oct 2020 20:21:09
User entered 'Yes (Y)'	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:20:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062'	System	07 Oct 2020 20:21:09
User entered '98.6'	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:20:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062'	System	07 Oct 2020 20:21:09
User entered 'Yes (Y)'	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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 'patient took 600mg Motrin PO, per conmed line 9 ' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 07:30:54
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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062' User entered '1'	Alandra White (b) (4)	05 Nov 2020 20:00:04
	System	07 Oct 2020 20:21:09
	System	07 Oct 2020 20:21:09
	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062'	System	07 Oct 2020 20:21:09
User entered '0'	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:06', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '201547b1-b8d1-4bf2-9110-98c6668a8062'	System	07 Oct 2020 20:21:09
User entered '07 Oct 2020 16:21'	System	07 Oct 2020 20:21:09

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 16:20'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 2'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:13', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8'	System	08 Oct 2020 16:00:42
User entered 'Yes (Y)'	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8'	System	08 Oct 2020 16:00:42
User entered '99.7'	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8'	System	08 Oct 2020 16:00:42
User entered 'Yes (Y)'	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

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 'patient took 600mg Motrin PO, per conmed line 9' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 07:31:07
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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:27', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8' User entered '1'	Alandra White (b) (4)	05 Nov 2020 20:00:11
	System	08 Oct 2020 16:00:42
	System	08 Oct 2020 16:00:42
	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:27', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8'	System	08 Oct 2020 16:00:42
User entered '0'	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:00:30', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9b676099-af23-4838-9314-67325cabdfd8'	System	08 Oct 2020 16:00:42
User entered '08 Oct 2020 12:00'	System	08 Oct 2020 16:00:42

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 3'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:56:59', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16'	System	09 Oct 2020 18:57:23
User entered 'Yes (Y)'	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:05', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16'	System	09 Oct 2020 18:57:23
User entered '99.0'	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16'	System	09 Oct 2020 18:57:23
User entered 'Yes (Y)'	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

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 'patient took 600mg Motrin PO, per conmed line 9' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 07:31:22
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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16'	Alandra White (b) (4)	05 Nov 2020 20:00:17
User entered '1'	System	09 Oct 2020 18:57:23
	System	09 Oct 2020 18:57:23
	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16'	System	09 Oct 2020 18:57:23
User entered '0'	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '15a982c9-a05d-4cfc-af6d-85e998802e16'	System	09 Oct 2020 18:57:23
User entered '09 Oct 2020 14:57'	System	09 Oct 2020 18:57:23

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 4'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:01:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9aed3c9c-53ad-4d31-95ff-11be38646d37'	System	10 Oct 2020 16:02:22
User entered 'Yes (Y)'	System	10 Oct 2020 16:02:22

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:13', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9aed3c9c-53ad-4d31-95ff-11be38646d37'	System	10 Oct 2020 16:02:22
User entered '98.6'	System	10 Oct 2020 16:02:22

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9aed3c9c-53ad-4d31-95ff-11be38646d37'	System	10 Oct 2020 16:02:22
User entered 'No (N)'	System	10 Oct 2020 16:02:22

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:20', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9aed3c9c-53ad-4d31-95ff-11be38646d37'	System	10 Oct 2020 16:02:22
User entered '10 Oct 2020 12:02'	System	10 Oct 2020 16:02:22

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 5'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9'	System	12 Oct 2020 13:42:59
User entered 'Yes (Y)'	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9' User entered '98.4'	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9'	System	12 Oct 2020 13:42:59
User entered 'Yes (Y)'	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

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 'patient took 600mg Motrin PO, per conmed line 9' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 07:32:07
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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9'	Alandra White (b) (4)	05 Nov 2020 20:00:26
User entered '1'	System	12 Oct 2020 13:42:59
	System	12 Oct 2020 13:42:59
	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9' User entered '0'	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b850cf6c-58be-4a15-8ed3-1602f8ffa6b9'	System	12 Oct 2020 13:42:59
User entered '12 Oct 2020 09:42'	System	12 Oct 2020 13:42:59

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 6'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:11', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f'	System	13 Oct 2020 00:22:32
User entered 'Yes (Y)'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:15', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f'	System	13 Oct 2020 00:22:32
User entered '98.4'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f'	System	13 Oct 2020 00:22:32
User entered 'Yes (Y)'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

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).	(b) (4), (b) (6)	09 Nov 2020 07:32:20
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 'patient took 600mg Motrin PO, per conmed line 9' (Site from System).	Alandra White (b) (4)	05 Nov 2020 20:00:33
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).	System	13 Oct 2020 00:22:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f'	System	13 Oct 2020 00:22:32
User entered '1'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f'	System	13 Oct 2020 00:22:32
User entered '0'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:27', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7d5b6794-db86-40a7-8b4b-65b728ee880f'	System	13 Oct 2020 00:22:32
User entered '12 Oct 2020 20:22'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 7'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '58ad0e63-71a1-4e06-8e3a-653fdf567f2d'	System	14 Oct 2020 10:01:47
User entered 'Yes (Y)'	System	14 Oct 2020 10:01:47

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '58ad0e63-71a1-4e06-8e3a-653fdf567f2d' User entered '99.1'	System	14 Oct 2020 10:01:47
	System	14 Oct 2020 10:01:47

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '58ad0e63-71a1-4e06-8e3a-653fdf567f2d'	System	14 Oct 2020 10:01:47
User entered 'No (N)'	System	14 Oct 2020 10:01:47

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '58ad0e63-71a1-4e06-8e3a-653fdf567f2d' User entered '14 Oct 2020 06:01'	System	14 Oct 2020 10:01:47
	System	14 Oct 2020 10:01:47

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:55'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 15:25'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7c289d9c-b707-445a-a0c6-e1a69f8429bc'	System	07 Oct 2020 20:22:37
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 20:22:37

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7c289d9c-b707-445a-a0c6-e1a69f8429bc'	System	07 Oct 2020 20:22:37
User entered 'No (N)'	System	07 Oct 2020 20:22:37

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:21:54', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7c289d9c-b707-445a-a0c6-e1a69f8429bc'	System	07 Oct 2020 20:22:37
User entered 'No (N)'	System	07 Oct 2020 20:22:37

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:17', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7c289d9c-b707-445a-a0c6-e1a69f8429bc'	System	07 Oct 2020 20:22:37
User entered 'None (1)'	System	07 Oct 2020 20:22:37

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7c289d9c-b707-445a-a0c6-e1a69f8429bc'	System	07 Oct 2020 20:22:37
User entered '07 Oct 2020 16:22'	System	07 Oct 2020 20:22:37

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 16:20'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 2'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:01:04', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '519872d0-e302-4d47-a8fd-679490b93265'	System	08 Oct 2020 16:02:56
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	08 Oct 2020 16:02:56

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:01:11', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '519872d0-e302-4d47-a8fd-679490b93265'	System	08 Oct 2020 16:02:56
User entered 'No (N)'	System	08 Oct 2020 16:02:56

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:01:22', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '519872d0-e302-4d47-a8fd-679490b93265'	System	08 Oct 2020 16:02:56
User entered 'No (N)'	System	08 Oct 2020 16:02:56

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '519872d0-e302-4d47-a8fd-679490b93265'	System	08 Oct 2020 16:02:56
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	08 Oct 2020 16:02:56

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '519872d0-e302-4d47-a8fd-679490b93265' User entered '08 Oct 2020 12:02'	System	08 Oct 2020 16:02:56
	System	08 Oct 2020 16:02:56

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 3'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:25', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b4943a31-0dd9-4b55-9057-25e81f16979e'	System	09 Oct 2020 18:57:40
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 18:57:40

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:27', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b4943a31-0dd9-4b55-9057-25e81f16979e'	System	09 Oct 2020 18:57:40
User entered 'No (N)'	System	09 Oct 2020 18:57:40

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b4943a31-0dd9-4b55-9057-25e81f16979e'	System	09 Oct 2020 18:57:40
User entered 'No (N)'	System	09 Oct 2020 18:57:40

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b4943a31-0dd9-4b55-9057-25e81f16979e' User entered 'None (1)'	System	09 Oct 2020 18:57:40
	System	09 Oct 2020 18:57:40

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:38', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b4943a31-0dd9-4b55-9057-25e81f16979e' User entered '09 Oct 2020 14:57'	System	09 Oct 2020 18:57:40
	System	09 Oct 2020 18:57:40

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 4'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c149b686-1749-4d37-8431-ad978c7b2fb4'	System	10 Oct 2020 16:02:39
User entered 'None (1)'	System	10 Oct 2020 16:02:39

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c149b686-1749-4d37-8431-ad978c7b2fb4'	System	10 Oct 2020 16:02:39
User entered 'No (N)'	System	10 Oct 2020 16:02:39

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:28', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c149b686-1749-4d37-8431-ad978c7b2fb4'	System	10 Oct 2020 16:02:39
User entered 'No (N)'	System	10 Oct 2020 16:02:39

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c149b686-1749-4d37-8431-ad978c7b2fb4'	System	10 Oct 2020 16:02:39
User entered 'None (1)'	System	10 Oct 2020 16:02:39

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c149b686-1749-4d37-8431-ad978c7b2fb4'	System	10 Oct 2020 16:02:39
User entered '10 Oct 2020 12:02'	System	10 Oct 2020 16:02:39

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 5'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:42:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'eb83a7f5-ff95-4fcd-9b3f-6f0c1bc2b876'	System	12 Oct 2020 13:43:10
User entered 'None (1)'	System	12 Oct 2020 13:43:10

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'eb83a7f5-ff95-4fcd-9b3f-6f0c1bc2b876'	System	12 Oct 2020 13:43:10
User entered 'No (N)'	System	12 Oct 2020 13:43:10

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'eb83a7f5-ff95-4fcd-9b3f-6f0c1bc2b876'	System	12 Oct 2020 13:43:10
User entered 'No (N)'	System	12 Oct 2020 13:43:10

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:03', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'eb83a7f5-ff95-4fcd-9b3f-6f0c1bc2b876'	System	12 Oct 2020 13:43:10
User entered 'None (1)'	System	12 Oct 2020 13:43:10

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:06', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'eb83a7f5-ff95-4fcd-9b3f-6f0c1bc2b876'	System	12 Oct 2020 13:43:10
User entered '12 Oct 2020 09:43'	System	12 Oct 2020 13:43:10

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 6'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:32', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'dab35aeb-c12c-4d6d-a86e-ec085866407f' User entered 'None (1)'	System	13 Oct 2020 00:22:43

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'dab35aeb-c12c-4d6d-a86e-ec085866407f'	System	13 Oct 2020 00:22:43
User entered 'No (N)'	System	13 Oct 2020 00:22:43

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'dab35aeb-c12c-4d6d-a86e-ec085866407f'	System	13 Oct 2020 00:22:43
User entered 'No (N)'	System	13 Oct 2020 00:22:43

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:38', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'dab35aeb-c12c-4d6d-a86e-ec085866407f' User entered 'None (1)'	System	13 Oct 2020 00:22:43

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'dab35aeb-c12c-4d6d-a86e-ec085866407f' User entered '12 Oct 2020 20:22'	System	13 Oct 2020 00:22:43

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 7'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9f570f69-1071-47af-8a5f-ec67986ca578'	System	14 Oct 2020 10:02:00
User entered 'None (1)'	System	14 Oct 2020 10:02:00

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:49', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9f570f69-1071-47af-8a5f-ec67986ca578'	System	14 Oct 2020 10:02:00
User entered 'No (N)'	System	14 Oct 2020 10:02:00

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9f570f69-1071-47af-8a5f-ec67986ca578'	System	14 Oct 2020 10:02:00
User entered 'No (N)'	System	14 Oct 2020 10:02:00

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

[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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9f570f69-1071-47af-8a5f-ec67986ca578'	System	14 Oct 2020 10:02:00
User entered 'None (1)'	System	14 Oct 2020 10:02:00

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:01:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '9f570f69-1071-47af-8a5f-ec67986ca578' User entered '14 Oct 2020 06:01'	System	14 Oct 2020 10:02:00
	System	14 Oct 2020 10:02:00

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:55'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 15:25'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:41', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae'	System	07 Oct 2020 20:23:03
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae'	System	07 Oct 2020 20:23:03
User entered 'No interference with activity (1)'	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae'	System	07 Oct 2020 20:23:03
User entered 'No interference with activity (1)'	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered 'None (0)'	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered 'None (0)'	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:54', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered 'None (0)'	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae'	System	07 Oct 2020 20:23:03
User entered 'No (N)'	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-07T16:22:59', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '0398228d-9b56-4623-9e87-473fe8424dae' User entered '07 Oct 2020 16:22'	System	07 Oct 2020 20:23:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 16:20'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 2'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:16', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411'	System	08 Oct 2020 16:03:33
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411'	System	08 Oct 2020 16:03:33
User entered 'Some interference with activity (2)'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411'	System	08 Oct 2020 16:03:33
User entered 'Some interference with activity (2)'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411'	System	08 Oct 2020 16:03:33
User entered 'Some interference with activity (2)'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411'	System	08 Oct 2020 16:03:33
User entered 'None (0)'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:31', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411'	System	08 Oct 2020 16:03:33
User entered 'None (0)'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411'	System	08 Oct 2020 16:03:33
User entered 'No (N)'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-08T12:02:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '080fb4c3-d0b1-4d27-998e-7fcde4e94411' User entered '08 Oct 2020 12:02'	System	08 Oct 2020 16:03:33

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 3'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:42', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'None (0)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'No interference with activity (1)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'Some interference with activity (2)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'Some interference with activity (2)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'None (0)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'None (0)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:57:58', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered 'No (N)'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-09T14:58:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'f82f0b7d-1f73-4436-82dd-a7d95cd1ec88'	System	09 Oct 2020 18:58:07
User entered '09 Oct 2020 14:58'	System	09 Oct 2020 18:58:07

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 4'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:36', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60'	System	10 Oct 2020 16:02:54
User entered 'None (0)'	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:38', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60'	System	10 Oct 2020 16:02:54
User entered 'None (0)'	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:40', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60'	System	10 Oct 2020 16:02:54
User entered 'None (0)'	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:42', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60'	System	10 Oct 2020 16:02:54
User entered 'None (0)'	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60'	System	10 Oct 2020 16:02:54
User entered 'None (0)'	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60'	System	10 Oct 2020 16:02:54
User entered 'None (0)'	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60'	System	10 Oct 2020 16:02:54
User entered 'No (N)'	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-10T12:02:49', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '6c795695-7c2f-4dc5-bde1-a8bd7e7bba60' User entered '10 Oct 2020 12:02'	System	10 Oct 2020 16:02:54
	System	10 Oct 2020 16:02:54

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 5'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db'	System	12 Oct 2020 13:43:48
User entered 'Any use of prescription pain reliever or prevents daily activity (3)'	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:27', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db'	System	12 Oct 2020 13:43:48
User entered 'No interference with activity (1)'	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:30', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered 'None (0)'	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db'	System	12 Oct 2020 13:43:48
User entered 'No interference with activity (1)'	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:35', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered 'None (0)'	System	12 Oct 2020 13:43:48
	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered 'None (0)'	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered 'No (N)'	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T09:43:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'ee280150-71d5-4c9c-a80b-c47c7d8611db' User entered '12 Oct 2020 09:43'	System	12 Oct 2020 13:43:48

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 6'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:22:53', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'No interference with activity (1)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:23:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'None (0)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:23:02', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'None (0)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:23:05', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered 'No (N)'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-12T20:23:07', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '04fe8883-d62c-487d-a96b-fd3072c536a0'	System	13 Oct 2020 00:23:10
User entered '12 Oct 2020 20:23'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Oct 2020 16:42:03
User entered 'Day 7'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:14', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e'	System	14 Oct 2020 10:02:34
User entered 'No interference with activity (1)'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:18', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e'	System	14 Oct 2020 10:02:34
User entered 'No interference with activity (1)'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:20', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'None (0)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:22', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'None (0)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:24', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'None (0)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:26', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'None (0)'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:28', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered 'No (N)'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-14T06:02:30', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '5429eaa6-b74d-4550-9144-14be80ea941e' User entered '14 Oct 2020 06:02'	System	14 Oct 2020 10:02:34
	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 16:42:03

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 00:23:10
User entered 'Day 8'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:33', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fabdf3d5-c77d-450b-ad60-08036d7e67c9'	System	15 Oct 2020 10:40:39
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fabdf3d5-c77d-450b-ad60-08036d7e67c9' User entered '15 Oct 2020 06:40'	System	15 Oct 2020 10:40:39
	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 10:02:34
User entered 'Day 9'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b14c58b5-7057-405f-b6a3-2737bc96b58d'	System	15 Oct 2020 16:00:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	15 Oct 2020 16:00:52

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:39', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'b14c58b5-7057-405f-b6a3-2737bc96b58d'	System	15 Oct 2020 16:00:52
User entered '15 Oct 2020 12:00'	System	15 Oct 2020 16:00:52

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 10:40:39
User entered 'Day 10'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:06:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1a7b128a-b5b9-4b3e-8621-291f5546544b' User entered 'None (0)'	System	16 Oct 2020 16:06:55
	System	16 Oct 2020 16:06:55

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:06:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1a7b128a-b5b9-4b3e-8621-291f5546544b' User entered '16 Oct 2020 12:06'	System	16 Oct 2020 16:06:55
	System	16 Oct 2020 16:06:55

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 00:23:10
User entered 'Day 8'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:42', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e2fe5970-42fc-4fb4-9ea5-ff826cd3b3cc'	System	15 Oct 2020 10:40:47
User entered 'No interference with activity (1)'	System	15 Oct 2020 10:40:47

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'e2fe5970-42fc-4fb4-9ea5-ff826cd3b3cc' User entered '15 Oct 2020 06:40'	System	15 Oct 2020 10:40:47
	System	15 Oct 2020 10:40:47

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:23:10

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 10:02:34
User entered 'Day 9'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:44', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c38fc664-66d0-4788-818e-0ae3a36aa69d'	System	15 Oct 2020 16:01:14
User entered 'No interference with activity (1)'	System	15 Oct 2020 16:01:14

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:46', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c38fc664-66d0-4788-818e-0ae3a36aa69d' User entered '15 Oct 2020 12:00'	System	15 Oct 2020 16:01:14
	System	15 Oct 2020 16:01:14

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 10:40:47
User entered 'Day 10'	System	15 Oct 2020 10:40:47

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:06:54', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '75cca891-999a-46a1-9651-8856f38508b9'	System	16 Oct 2020 16:07:05
User entered 'No interference with activity (1)'	System	16 Oct 2020 16:07:05

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:06:57', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '75cca891-999a-46a1-9651-8856f38508b9' User entered '16 Oct 2020 12:06'	System	16 Oct 2020 16:07:05
	System	16 Oct 2020 16:07:05

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 10:40:47

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 10:40:47

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 16:01:14
User entered 'Day 11'	System	15 Oct 2020 16:01:14

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-18T00:00:01', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1c380e7a-105e-4f7b-8c36-587bb807cd23'	System	18 Oct 2020 04:00:06
User entered 'None (0)'	System	18 Oct 2020 04:00:06

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-18T00:00:04', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '1c380e7a-105e-4f7b-8c36-587bb807cd23'	System	18 Oct 2020 04:00:06
User entered '18 Oct 2020 00:00'	System	18 Oct 2020 04:00:06

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:01:14

US3522529

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:01:14

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 00:22:32
User entered 'Day 8'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:48', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fe31633f-9d45-402e-ae12-c919e5355ce0'	System	15 Oct 2020 10:40:53
User entered 'No (N)'	System	15 Oct 2020 10:40:53

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T06:40:51', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'fe31633f-9d45-402e-ae12-c919e5355ce0' User entered '15 Oct 2020 06:40'	System	15 Oct 2020 10:40:53
	System	15 Oct 2020 10:40:53

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 00:22:32

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	14 Oct 2020 10:02:34
User entered 'Day 9'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:50', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7a00be97-d7a3-464f-af85-a62b7c42a7c0'	System	15 Oct 2020 16:01:15
User entered 'No (N)'	System	15 Oct 2020 16:01:15

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-15T12:00:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7a00be97-d7a3-464f-af85-a62b7c42a7c0'	System	15 Oct 2020 16:01:15
User entered '15 Oct 2020 12:00'	System	15 Oct 2020 16:01:15

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	14 Oct 2020 10:02:34

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Oct 2020 10:40:39
User entered 'Day 10'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:07:00', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7b6cf210-a966-4112-bcc2-cfd3f64311de' User entered 'No (N)'	System	16 Oct 2020 16:07:11

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-16T12:07:09', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '7b6cf210-a966-4112-bcc2-cfd3f64311de' User entered '16 Oct 2020 12:07'	System	16 Oct 2020 16:07:11
	System	16 Oct 2020 16:07:11

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 10:40:39

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Oct 2020 16:07:05
DataPoint Inactivated.	System	16 Oct 2020 16:06:55
Data entry locked.	System	15 Oct 2020 16:00:52
User entered 'Day 11'	System	15 Oct 2020 16:00:52

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-18T00:00:06', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '65ad3613-5971-42ad-ba42-37b80b15b43e'	System	18 Oct 2020 04:00:13
User entered 'No (N)'	System	18 Oct 2020 04:00:13
DataPoint Activated.	System	16 Oct 2020 16:07:05
DataPoint Inactivated.	System	16 Oct 2020 16:06:55

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-10-18T00:00:08', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '65ad3613-5971-42ad-ba42-37b80b15b43e'	System	18 Oct 2020 04:00:13
User entered '18 Oct 2020 00:00'	System	18 Oct 2020 04:00:13
DataPoint Activated.	System	16 Oct 2020 16:07:05
DataPoint Inactivated.	System	16 Oct 2020 16:06:55

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Oct 2020 16:07:05
DataPoint Inactivated.	System	16 Oct 2020 16:06:55
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 16:00:52

US3522529

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:32:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
DataPoint Activated.	System	16 Oct 2020 16:07:05
DataPoint Inactivated.	System	16 Oct 2020 16:06:55
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 16:00:52

US3522529

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 14:25:03

US3522529

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 14:25:03

US3522529

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 14:25:03

US3522529

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'See source. No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4), (b) (6)	14 Oct 2020 14:25:03

US3522529

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 14:25:10

US3522529

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 14:25:10

US3522529

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 17:16:31

US3522529

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 17:16:31

US3522529

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 17:16:31

US3522529

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 17:16:31

US3522529

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	21 Oct 2020 17:16:36

US3522529

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 17:16:36

US3522529

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	28 Oct 2020 18:58:26

US3522529

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Yaman Ahmed (b) (4) (b) (4)	28 Oct 2020 18:58:26

US3522529

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4) (b) (4)	28 Oct 2020 18:58:26

US3522529

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:32:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	Yaman Ahmed (b) (4) (b) (4)	28 Oct 2020 18:58:26

US3522529

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	28 Oct 2020 18:58:32

US3522529

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 18:58:32

US3522529

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:28:15

US3522529

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '5 Nov 2020'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:28:15

US3522529

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:28:15

US3522529

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	05 Nov 2020 17:28:15

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 03:40:16
Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' answered with 'k' (Site from DM).	Sharon Mathys (b) (4)	12 Nov 2020 14:02:33
User entered '05 Nov 2020' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	12 Nov 2020 14:02:29
User opened query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 09:13:33
User entered '5 Nov 2020'	Alayna Wilder (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:00'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '05 Nov 2020 12:00'	System	12 Nov 2020 14:02:29
User entered '5 Nov 2020 12:00'	System	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.1' F	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'temporal'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '80'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '18'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '125'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '62'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Nov 2020 17:29:01

US3522529

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:14

US3522529

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '5 Nov 2020'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:14

US3522529

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:26

US3522529

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '5 Nov 2020'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:26

US3522529

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '12:10'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:26

US3522529

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '5 Nov 2020 12:10'	System	05 Nov 2020 17:29:26

US3522529

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:29:31

US3522529

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:32:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 17:29:31

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 64'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-04T12:00:37', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c323c120-5614-46d9-818c-c52629984650'	System	04 Nov 2020 17:01:57
User entered 'No (N)'	System	04 Nov 2020 17:01:57

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-04T12:00:43', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c323c120-5614-46d9-818c-c52629984650'	System	04 Nov 2020 17:01:57
User entered 'No (N)'	System	04 Nov 2020 17:01:57

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-04T12:00:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c323c120-5614-46d9-818c-c52629984650' User entered '04 Nov 2020 12:00:47'	System	04 Nov 2020 17:01:57
	System	04 Nov 2020 17:01:57

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '02 Nov 2020 00:01'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '06 Nov 2020 23:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 71'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-09T06:27:45', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c0366b7d-88b8-480c-a983-c661c885c957'	System	09 Nov 2020 11:27:59
User entered 'No (N)'	System	09 Nov 2020 11:27:59

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-09T06:27:52', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c0366b7d-88b8-480c-a983-c661c885c957'	System	09 Nov 2020 11:27:59
User entered 'No (N)'	System	09 Nov 2020 11:27:59

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-09T06:27:55', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: 'c0366b7d-88b8-480c-a983-c661c885c957'	System	09 Nov 2020 11:27:59
User entered '09 Nov 2020 06:27:55'	System	09 Nov 2020 11:27:59

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '09 Nov 2020 00:01'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '13 Nov 2020 23:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered 'Day 78'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:19', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered 'Yes (Y)'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

Have you been exposed to someone with 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:29', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered 'No (N)'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:34', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered 'Yes (Y)'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered '0'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '1'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered '0'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered '1'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered '1'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered '0'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:47', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '0'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Please 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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:03:56', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

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 (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:04:06', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9'	System	16 Nov 2020 11:04:23
User entered 'No (N)'	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (FB15614A-6913-419D-BCA2-7AD934A38992)', Time: '2020-11-16T06:04:12', User OID: 'PatientReportedOutcome (US3522529)', ODM File OID: '160c2074-da43-4d36-9538-821c468d9ee9' User entered '16 Nov 2020 06:04:12'	System	16 Nov 2020 11:04:23
	System	16 Nov 2020 11:04:23

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '16 Nov 2020 00:01'	System	02 Sep 2020 16:46:18

US3522529

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:46:18
User entered '20 Nov 2020 23:59'	System	02 Sep 2020 16:46:18

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Oct 2020 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 Nov 2020 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 Nov 2020 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 Nov 2020 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 Nov 2020 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 Nov 2020 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 02:38:14

US3522529

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:32:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 02:38:14
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 02:38:14

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:56

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:35

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:56

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '15:30' reason for change: Data Entry Error	Sharon Mathys (b) (4)	19 Nov 2020 16:11:10
User entered '15:45'	Sharon Mathys (b) (4)	19 Nov 2020 16:06:35

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:56

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020 15:30'	System	19 Nov 2020 16:11:10
User entered '16 Nov 2020 15:45'	System	19 Nov 2020 16:06:35

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:56

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:35

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:32:56

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:06:35

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

[Date of Visit](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

[Date of Test](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

[Type of Test Performed](#)

Audit	User	Time (GMT)
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

[Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

[CLIA Certified?](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:33:44

US3522529

Folder: Covid-19 Assessment 16 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:32:56

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:33:44

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:32:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:48

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:32:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:48

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 26 Nov 2020 09:32:56

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:34:48

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:32:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:32:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 26 Nov 2020 09:32:56

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:32:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:32:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 26 Nov 2020 09:32:56

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:32:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:32:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 26 Nov 2020 09:32:56

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:32:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:32:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 26 Nov 2020 09:32:56

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:32:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:32:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 26 Nov 2020 09:32:56

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:32:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:32:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User entered 'NA (COVID-19 Negative) (NA)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 26 Nov 2020 09:32:56

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:36:29

US3522529

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Sharon Mathys (b) (4) (b) (4)	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '15:40'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '16 Nov 2020 15:40'	System	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '65' in	Sharon Mathys (b) (4)	19 Nov 2020 16:11:04
DataPoint set to visible.	(b) (4) System	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '175' lb	Sharon Mathys (b) (4)	19 Nov 2020 16:11:04
DataPoint set to visible.	(b) (4) System	18 Nov 2020 14:58:11

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.8' F	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '97'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '16'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '116'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '80'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 16:11:04

US3522529

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:13:08

US3522529

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:13:08

US3522529

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:32:56

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:13:22

US3522529

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:32:56

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	19 Nov 2020 16:13:22

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:34

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:34

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:34

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:32:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	24 Nov 2020 19:01:34

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:32:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:01:39

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:43

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:32:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:43

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:32:56

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:55

US3522529

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:32:56

[Date of Collection](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 19:01:55

US3522529

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:32:56

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:32
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:05:56

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:56:48
Un-reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:56:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:37
User entered 'USA-US131-2020-mRNA-1273-P301000006'	System	24 Sep 2020 01:47:33
User entered 'New'	(b) (4), (b) (6)	24 Sep 2020 01:47:33

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:03:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:03:25
Data point term sent to Coder	System	22 Oct 2020 17:18:09
DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:17:55
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:17:55
User entered 'Degenerative Disc Disease (Multilevel)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:17:55
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	08 Oct 2020 20:05:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:31:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:31:52
Data point term sent to Coder	System	24 Sep 2020 15:30:37
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:29:52
User entered 'HERNIAted Disc' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:29:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:08:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:08:47
Data point term sent to Coder	System	23 Sep 2020 22:07:58
User entered 'Hernia'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Sep 2020 15:29:52
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Sep 2020 15:30:11
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 15:30:11
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Sep 2020 15:30:11
User entered '23 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Sep 2020 15:30:11
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Sep 2020 15:29:52
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Sep 2020 15:29:52
User entered empty.	Sharon Mathys (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
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).		24 Sep 2020 15:29:52
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	24 Sep 2020 15:29:52
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Sep 2020 22:07:42
User entered '1'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '23 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Sep 2020 15:29:52
User entered empty.	Sharon Mathys (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'None (NONE)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	24 Sep 2020 15:29:52
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
	System	23 Sep 2020 22:08:40
User entered '1' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	23 Sep 2020 22:08:40
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Sep 2020 22:07:42
User entered '0'	Sharon Mathys (b) (4)	23 Sep 2020 22:07:42
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Sep 2020 15:29:52
User entered '0'	Sharon Mathys (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered '0'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:29:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:29
User entered empty.	Sharon Mathys (b) (4) (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates electrolyte level abnormalities for Calcium, Potassium and Magnesium. However, there are no corresponding AE record that match these conditions. Please update to record the corresponding AEs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:43:31
Query 'Per DM CLR: Narrative indicates electrolyte level abnormalities for Calcium, Potassium and Magnesium. However, there are no corresponding AE record that match these conditions. Please update to record the corresponding AEs as appropriate. Otherwise, clarify.' answered with 'previous query response: They were admitted for electrolyte abnormalities but endocrinologist assessment during stay determine the abnormalities was likely a lab error. Sub I does not feel this meets criteria since the condition was not actually present.' From narrative "ENDOCRINOLOGIST DETERMINED THAT THE ELECTROLYTE IMBALANCE WAS IN ACTUALITY A LAB ERROR "" (Site from DM).	Sharon Mathys (b) (4) (b) (4)	20 Nov 2020 19:49:02
User opened query 'Per DM CLR: Narrative indicates electrolyte level abnormalities for Calcium, Potassium and Magnesium. However, there are no corresponding AE record that match these conditions. Please update to record the corresponding AEs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 01:41:49
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 18:48:55
User closed query 'PV Query: It is currently reported that the subject was admitted for back pain and herniated disc, however the narrative in the report states the subject was admitted for electrolyte abnormalities. Please clarify the indication for admission to the hospital and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 18:51:56

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: It was reported that the subject was admitted for electrolyte abnormalities. Please assess if this meets criteria for AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 18:51:52
User closed query 'PV Query: Please provide any relevant laboratory and imaging diagnostic test results that confirmed the diagnosis of herniated disc. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 18:40:31
Query 'PV Query: It is currently reported that the subject was admitted for back pain and herniated disc, however the narrative in the report states the subject was admitted for electrolyte abnormalities. Please clarify the indication for admission to the hospital and update accordingly.' answered with 'They were admitted for electrolyte abnormalities but endocrinologist assessment during stay determine the abnormalities was likely a lab error. Sub I does not feel this meets criteria since the condition was not actually present. Reason for going to Hospital was (told to us at time) Herniated disc. During stay MRI diagnosed Degenerative Disc Disease (Multilevel)' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	23 Oct 2020 18:24:43
Query 'PV Query: It was reported that the subject was admitted for electrolyte abnormalities. Please assess if this meets criteria for AE/SAE reporting.' answered with 'They were admitted for electrolyte abnormalities but endocrinologist assessment during stay determine the abnormalities was likely a lab error. Sub I does not feel this meets criteria since the condition was not actually present.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	23 Oct 2020 18:23:54

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WENT TO HOSPITAL 9/21 AFTER PACKING AND MOVING RECENTLY AND DEVELEOPING SEVERE LOW BACK PAIN. WAS ADMITTED DUE TO ELECTROLYTE ABNORMALITIES IN LAB WITH CALCIUM 5.1, K + 3.1, MG 1.1. COVID 19 NP SWAB WAS GIVEN ON INTAKE AND RESULTS WERE NEGATIVE. NO NAUSEA/VOMITING/DIARRHEA. WAS GIVEN IV CORRECTION OF MAGNESIUM/POTASSIUM/CALCIUM. SENT HOME IN LATE AFTERNOON ON SEP 23, 2020 WITH PREDNISONE DOSE, ULTRAM AND ROBAXIN FOR PAIN. (SEE CONCOM. MEDS). FEELING BETTER, AND WANTS TO STILL PARTICIPATE IN TRIAL. During admittance, endocrinologist determined that the electolyte imbalance was in actuality a lab error due to rapid normalizaton of albumin levels in 12 hours.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	23 Oct 2020 18:21:35

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and imaging diagnostic test results that confirmed the diagnosis of herniated disc. Please include units and reference ranges if applicable.' answered with 'MRI OF THE LUMBAR SPINE WITHOUT CONTRAST History: Back pain and radiculopathy Comparison: None Technique: T1, T2 , STIR sagittal and T1 and T2 axial images of the lumbar spine have been performed. Comments: The lumbar vertebral body heights are maintained. The distal spinal cord is normal in signal and location. There is no bone marrow or ligament edema. There is degeneration of the disks and disc space narrowing at L3-L4 through L5-S1. The distal spinal cord terminates at L1. The spinal alignment is intact. Advanced degenerative change is worst at L4/L5. Schmorl's nodes are noted at L2 and T12. Axial images: T12-L1: No central canal stenosis. L1-L2: No central canal stenosis. L2-3: Mild disc bulge and facet degenerative change. No central canal stenosis. L3-L4: Mild disc bulge and facet degenerative change. No significant central canal stenosis. L4-L5: Diffuse disc bulge and facet hypertrophy. No central canal stenosis. Lateral bulges result in mild foraminal narrowing. L5-S1: Facet degenerative change is mild to moderate. There is no high-grade central canal stenosis. Lateral protrusions result in mild bilateral foraminal narrowing. The paraspinal soft tissues appear unremarkable. IMPRESSION: Multilevel degenerative change involving the disks and endplates. There is no large disc herniation or high-grade central canal stenosis. ' (Site from Safety). DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:19:05
	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:17:55

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WENT TO HOSPITAL 9/21 after PACKING AND MOVING RECENTLY AND DEVELEOPING SEVERE LOW BACK PAIN. WAS ADMITTED DUE TO ELECTROLYTE ABNORMALITIES IN LAB WITH CALCIUM 5.1, K + 3.1, MG 1.1. COVID 19 NP SWAB WAS GIVEN ON INTAKE AND RESULTS WERE NEGATIVE. NO NAUSEA/VOMITING/DIARRHEA. WAS GIVEN IV CORRECTION OF MAGNESIUM/POTASSIUM/CALCIUM. SENT HOME IN LATE AFTERNOON ON SEP 23, 2020 WITH PREDNISONE DOSE, ULTRAM AND ROBAXIN FOR PAIN. (SEE CONCOM. MEDS). FEELING BETTER, AND WANTS TO STILL PARTICIPATE IN TRIAL.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:17:55
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	15 Oct 2020 14:06:32
User opened query 'PV Query: It is currently reported that the subject was admitted for back pain and herniated disc, however the narrative in the report states the subject was admitted for electrolyte abnormalities. Please clarify the indication for admission to the hospital and update accordingly.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	15 Oct 2020 14:06:20
User opened query 'PV Query: It was reported that the subject was admitted for electrolyte abnormalities. Please assess if this meets criteria for AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	15 Oct 2020 14:06:05
User opened query 'PV Query: Please provide any relevant laboratory and imaging diagnostic test results that confirmed the diagnosis of herniated disc. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	15 Oct 2020 14:05:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	08 Oct 2020 20:05:29

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:57:23
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:57:19
Query 'PV Query: It is currently reported that the subject was admitted for back pain and herniated disc, however the narrative in the report states the subject was admitted for electrolyte abnormalities. Please clarify the indication for admission to the hospital and update accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:57:15
Query 'PV Query: It was reported that the subject was admitted for electrolyte abnormalities. Please assess if this meets criteria for AE/SAE reporting.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:57:13
Query 'PV Query: Please provide any relevant laboratory and imaging diagnostic test results that confirmed the diagnosis of herniated disc. Please include units and reference ranges if applicable.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 12:57:10
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with '9/21 np swab done on intake with negative results' (Site from Safety).	Sharon Mathys (b) (4)	06 Oct 2020 14:54:04

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'WENT TO HOSPITAL 9/21 FOR A HERNIATED DISC, AFTER PACKING AND MOVING RECENTLY AND DEVELOPING SEVERE LOW BACK PAIN. WAS ADMITTED DUE TO ELECTROLYTE ABNORMALITIES IN LAB WITH CALCIUM 5.1, K + 3.1, MG 1.1. Covid 19 NP swab was given on intake and results were negative. NO NAUSEA/VOMITING/DIARRHEA. WAS GIVEN IV CORRECTION OF MAGNESIUM/POTASSIUM/CALCIUM. SENT HOME IN LATE AFTERNOON ON SEP 23, 2020 WITH PREDNISONE DOSE, ULTRAM AND ROBAXIN FOR PAIN. (SEE CONCOM. MEDS). FEELING BETTER, AND WANTS TO STILL PARTICIPATE IN TRIAL.' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	06 Oct 2020 14:53:40
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:18:16
User opened query 'PV Query: It is currently reported that the subject was admitted for back pain and herniated disc, however the narrative in the report states the subject was admitted for electrolyte abnormalities. Please clarify the indication for admission to the hospital and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:18:01
User opened query 'PV Query: It was reported that the subject was admitted for electrolyte abnormalities. Please assess if this meets criteria for AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:16:45
User opened query 'PV Query: Please provide any relevant laboratory and imaging diagnostic test results that confirmed the diagnosis of herniated disc. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:16:34

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[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)	02 Oct 2020 17:16:27
User entered 'WENT TO HOSPITAL FOR A HERNIATED disc, after packing and moving recently and developing severe low back pain. Was admitted due to electrolyte abnormalities in lab with Calcium 5.1, K + 3.1, Mg 1.1. No nausea/vomiting/diarrhea. was given IV correction of Magnesium/potassium/calcium. sent home in late afternoon on sep 23, 2020 with prednisone dose, ultram and Robaxin for pain. (see concom. meds). Feeling better, and wants to still participate in trial.' reason for change: New Information	Sharon Mathys (b) (4)	24 Sep 2020 15:29:52
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Sep 2020 22:08:40
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	23 Sep 2020 22:08:40
User entered 'Went to hospital for a hernia, was admitted due to low electrolytes. Still in hospital at day of contact Sept 23rd.' reason for change: Per Query Resolution	Sharon Mathys (b) (4)	23 Sep 2020 22:08:40
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Sep 2020 22:07:42
User entered empty.	Sharon Mathys (b) (4)	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:32:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 22:07:42

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:42:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:42:26
Data point term sent to Coder	System	14 Oct 2020 14:40:44
User entered 'Headache day 8 and day 9'	(b) (4), (b) (6) (b) (4)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	14 Oct 2020 14:40:27
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 14:40:27
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	14 Oct 2020 14:39:45
User entered '11 Sep 2029'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	20 Nov 2020 19:46:50
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:45:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	20 Nov 2020 19:47:10
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'Updated to related to investigational product' (Site from DM).	Sharon Mathys (b) (4)	20 Nov 2020 19:47:05
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:41:08
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[None](#)

Audit	User	Time (GMT)
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		14 Oct 2020 14:40:07
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 14:40:07
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	14 Oct 2020 14:39:45
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT EXPERIENCED mild HEADACHE DAY 8 AND DAY 9.' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 14:40:07
User entered 'Patient experienced headache day 8 and day 9.'	(b) (4), (b) (6)	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:32:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 14:39:45

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:30:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 23:30:37
User closed query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of MUSCLE ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:15:19
Query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of MUSCLE ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'Updated to match eDiary Day 8 which pt forgot to complete.' (Site from DM).	Alandra White (b) (4) (b) (4)	05 Nov 2020 19:58:41
Data point term sent to Coder	System	05 Nov 2020 19:58:06
Coding entries removed.	Alandra White (b) (4) (b) (4)	05 Nov 2020 19:58:00
User entered 'MUSCLE ACHES ALL OVER BODY DAY 8' reason for change: Per Query Resolution	Alandra White (b) (4) (b) (4)	05 Nov 2020 19:58:00
User opened query 'Per DM CLR: Please review and update AE term to reflect the specific body location and type of MUSCLE ACHES. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:03:08
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:51:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:51:39
Data point term sent to Coder	System	14 Oct 2020 14:47:58
User entered 'Muscle aches day 8'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	20 Nov 2020 19:47:21
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:48:36
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'changed to not related and investigational product as related' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	20 Nov 2020 19:47:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	20 Nov 2020 19:47:21
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:41:28
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'patient states she is still experiencing mild muscle aches on day 8 after injection.'	(b) (4), (b) (6)	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:32:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 14:47:02

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:38:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:38:07
Data point term sent to Coder	System	24 Nov 2020 18:37:38
User entered 'Fatigue'	Sharon Mathys (b) (4)	24 Nov 2020 18:37:37
	(b) (4)	

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:39:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 18:39:10
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:39:10
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:37:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:39:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 18:39:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Nov 2020 18:39:10
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:37:37
User entered empty.	Sharon Mathys (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:39:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 18:39:10
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Nov 2020 18:39:10
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:37:37
User entered empty.	Sharon Mathys (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:39:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 18:39:10
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Nov 2020 18:39:10
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 18:37:37
User entered empty.	Sharon Mathys (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[None](#)

Audit	User	Time (GMT)
User entered '1'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Brought for Illness Visit. Cleared up in a few days and was negative for COVID-19 by NP swab'	Sharon Mathys (b) (4)	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:39:10

US3522529

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:32:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:37:37

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:39:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:39:03
Data point term sent to Coder	System	24 Nov 2020 18:38:41
User entered 'Nasal Congestion'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[None](#)

Audit	User	Time (GMT)
User entered '1'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Brought for Illness Visit. Cleared up in a few days and was negative for COVID-19 by NP swab'	Sharon Mathys (b) (4)	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 09:32:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:38:19

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:41:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 18:41:41
Data point term sent to Coder	System	24 Nov 2020 18:39:43
User entered 'Sore Throat'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[None](#)

Audit	User	Time (GMT)
User entered '1'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Brought for Illness Visit. Cleared up in a few days and was negative for COVID-19 by NP swab'	Sharon Mathys (b) (4)	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:38:53

US3522529

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 09:32:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 18:38:53

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:32:56

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:00:42

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:40:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:40:32
Data point term sent to Coder	System	23 Oct 2020 14:15:06
Data point term sent to Coder	System	23 Oct 2020 14:14:03
Coding entries removed.	(b) (4), (b) (6)	23 Oct 2020 14:13:30
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 13:57:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 13:57:43
Data point term sent to Coder	System	15 Sep 2020 13:02:50
User entered 'ibuprofen'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'MIGRAINES/HEADACHES/PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:14:07
User entered 'migraines/HEADACHES' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:13:30
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:08:29
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES did not meet the AE reporting criteria.' answered with 'new AE completed for unsolicited headache day 8 and day 9' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 14:41:40

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '800'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:13:30
User entered '4 Sep 2020'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:13:30
User entered '0'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 13:01:50

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: ZOLMITRIPTAN, PRODUCTSYNONYM: ZOMIG-ZMT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:11:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 14:11:37
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	23 Oct 2020 14:10:57 23 Oct 2020 14:10:16
User entered 'ZOMIG-ZMT' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:10:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: ZOLMITRIPTAN, PRODUCTSYNONYM: ZOMIG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:26:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 18:26:52
Data point term sent to Coder	System	16 Sep 2020 18:26:26
User entered 'Zomig'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'Migraines'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 18:26:23

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:56:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:56:23
Data point term sent to Coder	System	22 Oct 2020 17:09:58
User entered 'MAGNESIUM sulfate' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:09:24
Data point term sent to Coder	System	22 Oct 2020 17:06:52
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:06:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:28:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:28:47
Data point term sent to Coder	System	24 Sep 2020 15:31:38
User entered 'Magnesium'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 08:24:51
User entered 'Presumed ELECTROLYTE IMBALANCE' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:06:28
Query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'she states that it was administered as inpatient treatment but, 3-4 days later it was discovered it was due to lab error' (Site from DM).	(b) (4)	
User opened query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	Yaman Ahmed (b) (4)	21 Oct 2020 17:19:34
User entered 'Electrolyte Imbalance'	(b) (4)	
	Sharon Mathys (b) (4)	20 Oct 2020 15:31:22
	(b) (4)	
	Sharon Mathys (b) (4)	24 Sep 2020 15:31:15
	(b) (4)	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:09:24
User entered 'unknown'	Sharon Mathys (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'g (g)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:09:24
User entered 'Other (OTHER)'	Sharon Mathys (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:09:24
User entered 'unknown'	Sharon Mathys (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:09:24
User entered 'as needed (PRN)'	Sharon Mathys (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:09:24
User entered '23 Sep 2020'	Sharon Mathys (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:31:15

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:24:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:24:39
Data point term sent to Coder	System	12 Nov 2020 17:49:29
Datapoint queued for coding (5129522).	System	12 Nov 2020 17:48:34
Data point term sent to Coder	System	22 Oct 2020 17:12:01
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:11:25
User entered 'POTASSIUM chloride' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:11:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 06:20:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 06:20:21
Data point term sent to Coder	System	24 Sep 2020 15:39:08
User entered 'Potassium'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:42:52
User entered 'Presumed ELECTROLYTE IMBALANCE' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:12:43
Query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'she states that it was administered as inpatient treatment but, 3-4 days later it was discovered it was due to lab error' (Site from DM).	(b) (4)	
User opened query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	Yaman Ahmed (b) (4)	21 Oct 2020 17:19:41
User entered 'Electrolyte Imbalance'	(b) (4)	
	Sharon Mathys (b) (4)	20 Oct 2020 15:31:46
	(b) (4)	
	Sharon Mathys (b) (4)	24 Sep 2020 15:38:41
	(b) (4)	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:11:25
User entered 'unknown'	Sharon Mathys (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'meq' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:11:25
User entered 'unknown'	Sharon Mathys (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:11:25
User entered 'unknown (UNKNOWN)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:11:25
User entered '23 Sep 2020'	Sharon Mathys (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 17:11:25
User entered empty.	System	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 17:11:25
User entered empty.	System	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 17:11:25
User entered empty.	System	24 Sep 2020 15:38:41

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: CALCIUM GLUCONATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 19:54:36
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 Oct 2020 19:54:36
Data point term sent to Coder	System	22 Oct 2020 17:08:56
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:08:26
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:08:26
User entered 'CALCIUM gluconate' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:08:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:53:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:53:50
Data point term sent to Coder	System	24 Sep 2020 15:41:16
User entered 'Calcium'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:43:05
User entered 'Presumed ELECTROLYTE IMBALANCE' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:08:26
Query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'she states that it was administered as inpatient treatment but, 3-4 days later it was discovered it was due to lab error' (Site from DM).	(b) (4)	
User opened query 'Per CDM CR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	Yaman Ahmed (b) (4)	21 Oct 2020 17:19:47
User entered 'Electrolyte Imbalance'	(b) (4)	
	Sharon Mathys (b) (4)	20 Oct 2020 15:32:09
	(b) (4)	
	Sharon Mathys (b) (4)	24 Sep 2020 15:40:38
	(b) (4)	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:08:26
User entered 'unknown'	Sharon Mathys (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'g (g)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:08:26
User entered 'Other (OTHER)'	Sharon Mathys (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:08:26
User entered 'unknown'	Sharon Mathys (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:08:26
User entered 'as needed (PRN)'	Sharon Mathys (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:08:26
User entered '23 Sep 2020'	Sharon Mathys (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:40:38

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:12:03
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' answered with 'was taken for less than 14 days' (Site from DM).	Yaman Ahmed (b) (4)	21 Oct 2020 16:53:29
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (for corticosteroids ≥ 20 mg/day of prednisone equivalent).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 15:01:18
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Sep 2020 07:48:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Sep 2020 07:48:56
Data point term sent to Coder	System	24 Sep 2020 15:44:20
User entered 'Prednisone'	Sharon Mathys (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'Herniated Disc'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	21 Oct 2020 16:52:55
User entered '20'	Sharon Mathys (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)' reason for change:	Yaman Ahmed (b) (4)	21 Oct 2020 16:52:55
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Sharon Mathys (b) (4)	24 Sep 2020 15:43:28
	(b) (4)	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Yaman Ahmed (b) (4)	21 Oct 2020 16:52:55
User entered 'tapering dose'	Sharon Mathys (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:50:58
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Oct 2020 17:22:01
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4)	
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:50:58
User entered empty.	Sharon Mathys (b) (4)	24 Sep 2020 15:43:28
	(b) (4)	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:52:55
User entered empty.	System	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 16:52:55
User entered empty.	System	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 16:52:55
User entered empty.	System	24 Sep 2020 15:43:28

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:21:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:21:45
Data point term sent to Coder	System	29 Oct 2020 21:21:35
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 21:20:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:54:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:54:37
Data point term sent to Coder	System	07 Oct 2020 16:48:45
User closed query 'CDM-Coding: The trade name ULTRAM can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	07 Oct 2020 16:48:42
Query 'CDM-Coding: The trade name ULTRAM can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'Tramadol' (Site from System).	(b) (4), (b) (6)	07 Oct 2020 16:48:42
User entered 'Tramadol' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:48:33
User opened query 'CDM-Coding: The trade name ULTRAM can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:22:47
Data point term sent to Coder	System	24 Sep 2020 15:45:24
User entered 'Ultram'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:56:56
Query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:20:57
User entered 'Herniated disc' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 21:20:39
User opened query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 20:33:13
User entered 'Pain'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'four times daily (QID)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:48:33
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:48:33
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 15:44:37

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:23:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:23:46
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	29 Oct 2020 21:22:36 29 Oct 2020 21:21:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:45:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:45:53
Data point term sent to Coder User entered 'Robaxin'	System Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:25 24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 09:57:07
Query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 21:22:01
User entered 'herniated disc' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 21:21:49
User opened query 'Per CDM CR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 20:33:38
User entered 'Pain'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unknown'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:51:28
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 16:51:28
User entered empty.	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:45:20

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:59:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 16:59:33
Data point term sent to Coder	System	14 Oct 2020 14:43:49
User entered 'Motrin'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'Headache, muscle ache, joint pain'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '600'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '07 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 14:43:36

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE, PRODUCTSYNONYM: K-DUR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:09:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 08:09:30
Data point term sent to Coder	System	22 Oct 2020 17:21:16
User entered 'Kdur'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'Presumed Electrolyte imbalance'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'meq'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 17:21:07

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 17:31:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 17:31:22
Data point term sent to Coder	System	05 Nov 2020 17:30:46
User entered 'flu vaccine'	Alayna Wilder (b) (4)	05 Nov 2020 17:30:33
	(b) (4)	

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'influenza'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unk'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'unk'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

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

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:32:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 17:30:33

US3522529

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:32:56

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Oct 2020 16:53:05

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:32:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
User entered '23/Sep/2020 21:48'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:32:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered '1'	(b) (4), (b) (6)	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address:](#) State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:32:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
User entered '25/Sep/2020 14:45'	System	25 Sep 2020 14:45:08

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:32:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 15:09:16
User entered '1'	(b) (4), (b) (6)	25 Sep 2020 14:45:08

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address:](#) City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:32:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
User entered '07/Oct/2020 13:01'	System	07 Oct 2020 13:01:03

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:32:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 18:39:53
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
User entered '1'	(b) (4), (b) (6)	07 Oct 2020 13:01:03

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:49
Un-reviewed for Safety.	(b) (4), (b) (6)	07 Oct 2020 13:00:45
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'USA-US131-2020-MRNA-1273-P301000006'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Yes (Y)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'No (N)'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Paul'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'Kilgore'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address:](#) [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered 'MI'	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:47:54
User entered (b) (6)	System	24 Sep 2020 01:47:33

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:05:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:44:51
User entered 'US'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 26 Nov 2020 09:32:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Oct 2020 18:40:10
User entered '3'	System	07 Oct 2020 13:01:03
User entered '2'	System	25 Sep 2020 14:45:08
User entered '1'	System	24 Sep 2020 01:48:02

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:32:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Oct/2020 18:40'	System	23 Oct 2020 18:40:10

US3522529

Folder: SAE USA-US131-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:32:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 18:40:10