

US3522269 (Prod: Henry Ford Health System)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:33:08

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US3522269

Form: Participant Creation

Generated On: 26 Nov 2020 09:33:08

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

Date of Birth (MMM yyyy)	(b) (6) 1976
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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:33:08

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:33:08

Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	21 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:26 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 08:26
Height (<i>xxx.x</i>)	62 in
Weight (<i>xxx.x</i>)	120.8 lb
BMI (<i>xxx.x</i>)	22.14081 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:33:08

Date of assessment (*dd MMM yyyy*) 21 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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	True
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:08

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 106826

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:08

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

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)	21 AUG 2020
Time of assessment (00:00-23:59)	08:26 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 08:26
Temperature (xxx.x)	97.7 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

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)	21 AUG 2020
Time of assessment (00:00-23:59)	10:05 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:05
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:08

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed _____ Urine ☐

Serum ☐

Result _____ Positive ☐

Negative ☐

Was FSH sample collected? Yes ☐

No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 AUG 2020

What was the treatment time? (00:00-23:59) 09:35 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 09:35

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 AUG 2020

Collection time (00:00-23:59)

09:13 (24 HR)

Collection date and time (derived)

21 AUG 2020 09:13

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:33:08

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:15	21 AUG 2020 09:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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

21 AUG 2020 10:06

PC Open Date & Time

21 AUG 2020 09:55

PC Close Date & Time

21 AUG 2020 12:25

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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 98.8 °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	21 AUG 2020 16:44
PC Open Date & Time	21 AUG 2020 13:20
PC Close Date & Time	22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 16:04

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

23 AUG 2020 12:04

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 13:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:04

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

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):

PC Time Stamp

26 AUG 2020 13:08

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

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

98.5 °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

27 AUG 2020 13:05

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 11:35

PC Open Date & Time

21 AUG 2020 09:55

PC Close Date & Time

21 AUG 2020 12:25

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 16:44

PC Open Date & Time

21 AUG 2020 13:20

PC Close Date & Time

22 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 16:04

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 12:04

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 13:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

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 ☐

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

2

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)**

5

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 12:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

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 ☐

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

3

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)**

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 13:10

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 13:06

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 11:36
PC Open Date & Time	21 AUG 2020 09:55
PC Close Date & Time	21 AUG 2020 12:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 16:45
PC Open Date & Time	21 AUG 2020 13:20
PC Close Date & Time	22 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	22 AUG 2020 16:05
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	23 AUG 2020 12:05
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	24 AUG 2020 13:41
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	25 AUG 2020 12:07
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	26 AUG 2020 13:11
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	27 AUG 2020 13:06
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 8

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 9

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3522269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

ATTEMPTED TO REACH
PATIENT WITH NO SUCCESS.
WILL ATTEMPT AT LATER
TIME.

If Contact Not Made, please provide Comments

US3522269

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522269

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

CONTACT NOT MADE;
VOICEMAIL LEFT

If Contact Not Made, please provide Comments

US3522269

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522269

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

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 1ST ATTEMPT 11 SEP 2020; 2ND
ATTEMPT 15 SEP 2020; 3RD
If Contact Not Made, please provide Comments ATTEMPT 16 SEP 2020

US3522269

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522269

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	13:47 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 13:47
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	22 SEP 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 14:45
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	TEMPORAL
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3522269

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:08

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

Was the pregnancy test performed?	Yes ☒
	No ☐
Date of test (<i>dd MMM yyyy</i>)	22 SEP 2020
Test performed	Urine ☒
	Serum ☐
Result	Positive ☐
	Negative ☒
Was FSH sample collected?	Yes ☐
	No ☒
Collection date	22 SEP 2020
Collection time	13:32
Collection date and time (derived)	22 SEP 2020 13:32

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 14:15 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 14:15

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3522269

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	22 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:10 (24 HR)
Collection date and time (derived)	22 SEP 2020 14:10

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:33:08

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:12	22 SEP 2020 14:12
Nasopharyngeal Swab 2	No		

US3522269

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 14:51

PC Open Date & Time

22 SEP 2020 13:35

PC Close Date & Time

22 SEP 2020 16:05

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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 99.0 °F

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

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

PC Time Stamp	22 SEP 2020 18:57
PC Open Date & Time	22 SEP 2020 17:00
PC Close Date & Time	23 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 12:27

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

24 SEP 2020 12:57

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

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

98.8 °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

25 SEP 2020 12:38

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

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

98.7 °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

26 SEP 2020 12:05

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

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):

PC Time Stamp

27 SEP 2020 12:36

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

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

98.6 °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

28 SEP 2020 12:04

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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

22 SEP 2020 14:51

PC Open Date & Time

22 SEP 2020 13:35

PC Close Date & Time

22 SEP 2020 16:05

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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

22 SEP 2020 18:58

PC Open Date & Time

22 SEP 2020 17:00

PC Close Date & Time

23 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

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

23 SEP 2020 12:27

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

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

24 SEP 2020 12:58

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

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

25 SEP 2020 12:38

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

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

26 SEP 2020 12:05

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

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

27 SEP 2020 12:37

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

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

28 SEP 2020 12:04

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 14:51
PC Open Date & Time	22 SEP 2020 13:35
PC Close Date & Time	22 SEP 2020 16:05

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 18:58
PC Open Date & Time	22 SEP 2020 17:00
PC Close Date & Time	23 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	23 SEP 2020 12:27
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	24 SEP 2020 12:58
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	25 SEP 2020 12:38
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	26 SEP 2020 12:06
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	27 SEP 2020 12:37
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

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 ☒

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

Yes ☐	
PC Time stamp	28 SEP 2020 12:05
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3522269

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3522269

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522269

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

Was Contact Attempted? Yes ☒ No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 07 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

FLU VACCINE RECEIVED 05
OCT 2020. NO ONGOING OR
NEW AE REPORTED, NO NEW
ILLNESS OR HOSPITAL VISITS;
NO CHANGES IN HEALTH
STATUS, MEDICATIONS,
COVID-19 EXPOSURE OR
PREGNANCY RISK

US3522269

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522269

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3522269

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522269

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

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 _____

US3522269

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

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)	

US3522269

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:08

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.

US3522269

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00-23:59</i>)	
Collection date and time (derived)	

US3522269

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 NOV 2020 00:01

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12 NOV 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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

Date and time of submission

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15 NOV 2020 00:01

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19 NOV 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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26 NOV 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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17 DEC 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

24 DEC 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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31 DEC 2020 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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07 JAN 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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21 JAN 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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11 FEB 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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

Date and time of submission

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07 MAR 2021 00:01

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11 MAR 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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18 MAR 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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°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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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02 JUN 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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09 JUN 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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16 JUN 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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23 JUN 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 JUL 2022 00:01

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07 JUL 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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14 JUL 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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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17 JUL 2022 00:01

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21 JUL 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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28 JUL 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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04 AUG 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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

Date and time of submission

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07 AUG 2022 00:01

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11 AUG 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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18 AUG 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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°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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

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25 AUG 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

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

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3522269

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:33:08

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

US3522269

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:33:08

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3522269

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:33:08

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

AEID	USA-US131-2020-MRNA-1273-P30 1000005
Adverse event	NAUSEA
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)	7 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)	15 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)	12 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	16 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	333 of 1712

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

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	

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

NAUSEA ONSET 7-SEP-2020, GRADUAL AND GOT WORSE OVER THE FOLLOWING DAYS, VOMITING AND ABDOMINAL PAIN STARTED 8-SEP-2020, AND GOT WORSE THE NEXT FEW DAYS. SHE DROVE HERSELF TO THE WINDSOR REGIONAL HOSPITAL ON 11-SEP-2020 OR 12-SEP-2020, SHE COULD NOT REMEMBER THE DATE. AT THE TIME, THE VOMITING WAS SEVERE, SHE VOMITED ANY TIME THAT SHE TRIED TO EAT SOMETHING, AT LEAST 5-10 TIMES THAT DAY, AND WAS DRY HEAVING AT SEVERAL OTHER POINTS

THE HOSPITAL WAS CONCERNED ABOUT GALLSTONES. SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020 AND THEN SHE HAD TO WAIT TO GET THE MRCP UNTIL 12-SEP-2020 OR 13-SEP-2020, BUT THE RESULTS CAME BACK SHOWING NO GALLSTONES. THEY DID FIND THAT SHE HAD DILATED BILE DUCTS. SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. SHE WAS GIVEN IV REPLACEMENT. OVER THE NEXT DAY OR TWO, HER VOMITING AND NAUSEA RESOLVED, AND LIQUID THEN

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

SOLID FOOD WAS
REINTRODUCED AND
TOLERATED OK.SHE WAS
DISCHARGED 16-SEP-2020.
THEY DID NOT DISCHARGE
HER ON ANY CHRONIC OR
ONGOING MEDICATIONS. THE
NAUSEA AND VOMITING HAD
COMPLETELY RESOLVED AT
THAT POINT.
ZOFTRAN 1 TAB PO AS NEEDED,
START DATE 9/12/20- STOP
DATE 9/14/20 (APPROXIMATE
DATES)
MORPHINE 1 TAB PO AS
NEEDED, START DATE 9/12/20-
STOP DATE 9/13/20
(APPROXIMATE DATES)
PROTONIX, 1 TAB PO DAILY,
START DATE 9/12/20- STOP
DATE 9/16/20 (APPROXIMATE
DATES)
POTASSIUM, IV, AS NEEDED,
START DATE 9/12/20- STOP
DATE 9/13/20 (APPROXIMATE
DATES)
MAGNESIUM IV, AS NEEDED,
START DATE 9/12/20- STOP
DATE 9/13/20 (APPROXIMATE
DATES)
CALCIUM 1 TAB PO DAILY,
START DATE 9/14/20- STOP
DATE 9/16/20 (APPROXIMATE
DATES)

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

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

AEID	USA-US131-2020-MRNA-1273-P30 1000005
Adverse event	ABDOMINAL PAIN
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)	8 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)	15 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)	12 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	16 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	337 of 1712

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

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	

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

VOMITING AND ABDOMINAL PAIN STARTED 8-SEP-2020, AND GOT WORSE THE NEXT FEW DAYS. SHE DROVE HERSELF TO THE WINDSOR REGIONAL HOSPITAL ON 11-SEP-2020 OR 12-SEP-2020, SHE COULD NOT REMEMBER THE DATE. AT THE TIME, THE VOMITING WAS SEVERE, SHE VOMITED ANY TIME THAT SHE TRIED TO EAT SOMETHING, AT LEAST 5-10 TIMES THAT DAY, AND WAS DRY HEAVING AT SEVERAL OTHER POINTS

THE HOSPITAL WAS CONCERNED ABOUT GALLSTONES. SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020 AND THEN SHE HAD TO WAIT TO GET THE MRCP UNTIL 12-SEP-2020 OR 13-SEP-2020, BUT THE RESULTS CAME BACK SHOWING NO GALLSTONES. THEY DID FIND THAT SHE HAD DILATED BILE DUCTS. SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. SHE WAS GIVEN IV REPLACEMENT. OVER THE NEXT DAY OR TWO, HER VOMITING AND NAUSEA RESOLVED, AND LIQUID THEN SOLID FOOD WAS REINTRODUCED AND TOLERATED OK. SHE WAS DISCHARGED 16-SEP-2020. THEY DID NOT DISCHARGE HER ON ANY CHRONIC OR ONGOING MEDICATIONS. THE NAUSEA AND VOMITING HAD COMPLETELY RESOLVED AT THAT POINT.

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

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

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

AEID	USA-US131-2020-MRNA-1273-P30 1000005
Adverse event	VOMITING
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)	8 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)	15 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)	12 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	16 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	341 of 1712

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

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	

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

VOMITING AND ABDOMINAL PAIN STARTED 8-SEP-2020, AND GOT WORSE THE NEXT FEW DAYS. SHE DROVE HERSELF TO THE WINDSOR REGIONAL HOSPITAL ON 11-SEP-2020 OR 12-SEP-2020, SHE COULD NOT REMEMBER THE DATE. AT THE TIME, THE VOMITING WAS SEVERE, SHE VOMITED ANY TIME THAT SHE TRIED TO EAT SOMETHING, AT LEAST 5-10 TIMES THAT DAY, AND WAS DRY HEAVING AT SEVERAL OTHER POINTS

THE HOSPITAL WAS CONCERNED ABOUT GALLSTONES. SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020 AND THEN SHE HAD TO WAIT TO GET THE MRCP UNTIL 12-SEP-2020 OR 13-SEP-2020, BUT THE RESULTS CAME BACK SHOWING NO GALLSTONES. THEY DID FIND THAT SHE HAD DILATED BILE DUCTS. SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. SHE WAS GIVEN IV REPLACEMENT. OVER THE NEXT DAY OR TWO, HER VOMITING AND NAUSEA RESOLVED, AND LIQUID THEN SOLID FOOD WAS REINTRODUCED AND TOLERATED OK. SHE WAS

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

DISCHARGED 16-SEP-2020.
THEY DID NOT DISCHARGE
HER ON ANY CHRONIC OR
ONGOING MEDICATIONS. THE
NAUSEA AND VOMITING HAD
COMPLETELY RESOLVED AT
THAT POINT.
ZOFTRAN 1 TAB PO AS NEEDED,
START DATE 9/12/20- STOP
DATE 9/14/20 (APPROXIMATE
DATES)
MORPHINE 1 TAB PO AS
NEEDED, START DATE 9/12/20-
STOP DATE 9/13/20
(APPROXIMATE DATES)
PROTONIX, 1 TAB PO DAILY,
START DATE 9/12/20- STOP
DATE 9/16/20 (APPROXIMATE
DATES)
POTASSIUM, IV, AS NEEDED,
START DATE 9/12/20- STOP
DATE 9/13/20 (APPROXIMATE
DATES)
MAGNESIUM IV, AS NEEDED,
START DATE 9/12/20- STOP
DATE 9/13/20 (APPROXIMATE
DATES)
CALCIUM 1 TAB PO DAILY,
START DATE 9/14/20- STOP
DATE 9/16/20 (APPROXIMATE
DATES)

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

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:33:08

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

Yes ☒

No ☐

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

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

Name of Medication	ZOFRAN
Prophylaxis	Yes ☐ No ☒
Indication	NAUSEA
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 ☐

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

	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)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 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 ☐

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ☒
Indication	ABDOMINAL PAIN
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 ☐

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

	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)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 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 ☐

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

Name of Medication	PANTOPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	NAUSEA
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 ☐

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

	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)	12 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		16 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 ☒	

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

Name of Medication	POTASSIUM IV
Prophylaxis	Yes ☐ No ☒
Indication	ELECTROLYTE REPLACEMENT FOR VOMITING
Dose per administration	UNKNOWN
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	IV BAG
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 ☐

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

	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)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 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	☐

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

Name of Medication	MAGNESIUM IV
Prophylaxis	Yes ☐ No ☒
Indication	ELECTROLYTE REPLACEMENT FOR VOMITING
Dose per administration	UNKNOWN
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	IV DRIP
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 ☐

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

	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)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		13 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	☐

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

Name of Medication	CALCIUM
Prophylaxis	Yes ☐ No ☒
Indication	ELECTROLYTE REPLACEMENT FOR VOMITING
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 ☐

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

	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)		14 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 16 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	☒

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☐ No ☒
Indication	FLU VACCINATION
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

	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)		5 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		5 OCT 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 ☐

US3522269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:33:08

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3522269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:33:08

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

US3522269

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:33:08

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

US3522269

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:33:08

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 ☐

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

SAEID	USA-US131-2020-MRNA-1273-P301000005
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)	3

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:33:08

SAEID	USA-US131-2020-MRNA-1273-P301000005
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)	3
Date of submission (Pre-filled from custom function)	23/SEP/2020 07:53
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

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:33:08

SAEID	USA-US131-2020-MRNA-1273-P301000005
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)	3
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:28
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

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:33:08

SAEID	USA-US131-2020-MRNA-1273-P301000005
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)	3
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:50
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

US3522269 (Prod: Henry Ford Health System)

US3522269

Form: Participant Creation

Generated On: 26 Nov 2020 09:33:08

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3522269'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Aug 2020 12:14:11

US3522269

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:24:52

US3522269

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Aug 2020 12:14:12

US3522269

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Aug 2020 12:24:52

US3522269

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	21 Aug 2020 12:24:52

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered (b) (6) 1976'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Aug 2020 12:14:13

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Age](#)

Audit	User	Time (GMT)
User entered '44'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '44'	System	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:33:08

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:26:02

US3522269

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '2020'	System	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)' reason for change:	Sharon Mathys (b) (4)	04 Sep 2020 15:13:29
Data Entry Error	(b) (4)	
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:26:29

US3522269

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	21 Aug 2020 12:14:12

US3522269

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:33:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 12:26:34

US3522269

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:26:34

US3522269

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:33:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:26:40

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '08:26'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 Aug 2020 08:26'	System	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '62' in	(b) (4), (b) (6)	21 Aug 2020 12:32:57
DataPoint set to visible.	System	21 Aug 2020 12:26:34

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '120.8' lb reason for change: Data Entry Sharon Mathys (b) (4)	(b) (4)	24 Sep 2020 15:57:26
Error	(b) (4)	
User entered '120.8' kg	(b) (4), (b) (6)	21 Aug 2020 12:32:57
DataPoint set to visible.	System	21 Aug 2020 12:26:34

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '22.14081'	System	24 Sep 2020 15:57:26
Amendment Manager: User entered '48.70977'	System	17 Sep 2020 00:17:35
User closed query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 15:34:41
Query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' answered with 'wrong cohort' (Site from System).	Sharon Mathys (b) (4)	25 Aug 2020 15:34:12
User opened query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).	(b) (4)	
User entered '48.7'	System	21 Aug 2020 12:32:57
DataPoint set to visible.	System	21 Aug 2020 12:26:34

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	21 Aug 2020 12:32:57
DataPoint set to visible.	System	21 Aug 2020 12:26:34

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4)	25 Aug 2020 15:34:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered '97.7' F	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered 'Other (Other)'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	25 Aug 2020 15:34:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered 'temporal'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered '81'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered '15'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered '120'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:00:31
User entered '80'	(b) (4), (b) (6)	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:33:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 12:32:57

US3522269

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:33:06

US3522269

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:33:06

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:33:08

[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	25 Aug 2020 15:33:03
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	21 Aug 2020 12:33:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:33:08

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	25 Aug 2020 15:33:03
User entered '7 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:33:08

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:33:57

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Collection date](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	25 Aug 2020 15:32:36
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Collection time](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	25 Aug 2020 15:32:36
User entered '08:40' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 12:41:51
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 15:32:36
User entered '21 Aug 2020 08:40'	System	21 Aug 2020 12:41:51
User entered empty.	System	21 Aug 2020 12:39:39

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:33:08

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:40:26

US3522269

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:40:44

US3522269

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:40:44

US3522269

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Aug 2020 12:40:44

US3522269

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	21 Aug 2020 12:40:44

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Aug 2020 12:14:14

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '106826'	RWS_ENDPOINT ENDPOINT (b) (4) 	21 Aug 2020 12:14:14

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:08

[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]	21 Aug 2020 12:14:14

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:41:00

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:08

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)	21 Aug 2020 12:41:00

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User closed query 'Severe obesity is recorded as Yes, System but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).		24 Sep 2020 15:57:51
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	24 Sep 2020 15:57:51
User opened query 'Severe obesity is recorded as Yes, but Cohort group is not recorded as 'at risk'. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	System	25 Aug 2020 15:33:42
User entered 'No (N)'	Sharon Mathys (b) (4)	25 Aug 2020 15:33:42
	(b) (4)	
	(b) (4), (b) (6)	21 Aug 2020 12:41:00

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:41:00

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:08

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:41:00

US3522269

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'No (N)'	Sharon Mathys (b) (4)	24 Sep 2020 15:57:51
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:37:50
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:55:08

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:08

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '62' in	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:08

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:03:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '120.8' lb	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:08

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '62' in	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:08

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:03:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '120.8' lb	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '08:26'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 Aug 2020 08:26'	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'temporal'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '15'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '120'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:08

[Height](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '62' in	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:33:08

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:03:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 15:02:25
User entered '120.8' lb	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 14:06:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Aug 2020 14:06:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Aug 2020 12:43:13
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '10:05' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 Aug 2020 10:05'	System	21 Aug 2020 14:06:50
User entered empty.	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 14:07:04
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:07:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 14:06:50
User entered '98.1' (non-conformant).	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '76' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Aug 2020 14:06:50
User entered empty.	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Aug 2020 14:06:50
User entered empty.	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '106' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 14:06:50
User entered empty.	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 14:06:50
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Aug 2020 14:06:50
User entered empty.	System	21 Aug 2020 12:43:13

US3522269

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	04 Sep 2020 15:12:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:43:26

US3522269

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	04 Sep 2020 15:12:42
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:43:26

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 16:41:16
Query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' answered with 'done' (Site from DM).	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:28:54
User entered 'No (N)' reason for change: Data Entry Error	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:28:51
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:07:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4)	01 Sep 2020 12:28:51
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Test performed](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4)	01 Sep 2020 12:28:51
User entered 'Urine (URINE)'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Result](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4)	01 Sep 2020 12:28:51
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Collection date](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4)	01 Sep 2020 12:28:51
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Collection time](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tyler Prentiss (b) (4)	01 Sep 2020 12:28:51
User entered '08:40'	(b) (4), (b) (6)	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 12:28:51
User entered '21 Aug 2020 08:40'	System	21 Aug 2020 12:43:44

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '09:35'	(b) (4), (b) (6)	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 Aug 2020 09:35'	System	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 13:26:24

US3522269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:17:30

US3522269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 13:17:30

US3522269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '09:13'	(b) (4), (b) (6)	21 Aug 2020 13:17:30

US3522269

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 Aug 2020 09:13'	System	21 Aug 2020 13:17:30

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:15'	(b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '21 Aug 2020 09:15'	System	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 13:17:46

US3522269

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 12:45:15

US3522269

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 12:45:15

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T10:00:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b2bdd2d2-1830-4981-8057-28b071b45a41'	System	21 Aug 2020 14:06:29
User entered 'Yes (Y)'	System	21 Aug 2020 14:06:29

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T10:06:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b2bdd2d2-1830-4981-8057-28b071b45a41'	System	21 Aug 2020 14:06:29
User entered '98.1'	System	21 Aug 2020 14:06:29

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T10:06:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b2bdd2d2-1830-4981-8057-28b071b45a41'	System	21 Aug 2020 14:06:29
User entered 'No (N)'	System	21 Aug 2020 14:06:29

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T10:06:24', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b2bdd2d2-1830-4981-8057-28b071b45a41'	System	21 Aug 2020 14:06:29
User entered '21 Aug 2020 10:06'	System	21 Aug 2020 14:06:29

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 09:55'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:25'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:42:51', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '297e4493-ce85-4c79-8261-ee2f84134363'	System	21 Aug 2020 20:44:28
User entered 'Yes (Y)'	System	21 Aug 2020 20:44:28

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '297e4493-ce85-4c79-8261-ee2f84134363'	System	21 Aug 2020 20:44:28
User entered '98.8'	System	21 Aug 2020 20:44:28

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:18', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '297e4493-ce85-4c79-8261-ee2f84134363'	System	21 Aug 2020 20:44:28
User entered 'No (N)'	System	21 Aug 2020 20:44:28

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '297e4493-ce85-4c79-8261-ee2f84134363'	System	21 Aug 2020 20:44:28
User entered '21 Aug 2020 16:44'	System	21 Aug 2020 20:44:28

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 13:20'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 2'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:03:53', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35ceb7db-c487-4b24-a985-bd215b1c20c3'	System	22 Aug 2020 20:04:41
User entered 'Yes (Y)'	System	22 Aug 2020 20:04:41

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:28', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35ceb7db-c487-4b24-a985-bd215b1c20c3'	System	22 Aug 2020 20:04:41
User entered '97.7'	System	22 Aug 2020 20:04:41

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:33', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35ceb7db-c487-4b24-a985-bd215b1c20c3'	System	22 Aug 2020 20:04:41
User entered 'No (N)'	System	22 Aug 2020 20:04:41

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35ceb7db-c487-4b24-a985-bd215b1c20c3'	System	22 Aug 2020 20:04:41
User entered '22 Aug 2020 16:04'	System	22 Aug 2020 20:04:41

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 3'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '637f6cad-2064-4925-b389-e22a48befd02'	System	23 Aug 2020 16:04:39
User entered 'Yes (Y)'	System	23 Aug 2020 16:04:39

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:26', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '637f6cad-2064-4925-b389-e22a48befd02'	System	23 Aug 2020 16:04:39
User entered '98.8'	System	23 Aug 2020 16:04:39

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:29', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '637f6cad-2064-4925-b389-e22a48befd02'	System	23 Aug 2020 16:04:39
User entered 'No (N)'	System	23 Aug 2020 16:04:39

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '637f6cad-2064-4925-b389-e22a48befd02'	System	23 Aug 2020 16:04:39
User entered '23 Aug 2020 12:04'	System	23 Aug 2020 16:04:39

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 4'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '50fb3630-1c70-4725-9aad-c21b677e7e6f'	System	24 Aug 2020 17:40:35
User entered 'Yes (Y)'	System	24 Aug 2020 17:40:35

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:22', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '50fb3630-1c70-4725-9aad-c21b677e7e6f'	System	24 Aug 2020 17:40:35
User entered '98.2'	System	24 Aug 2020 17:40:35

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:27', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '50fb3630-1c70-4725-9aad-c21b677e7e6f'	System	24 Aug 2020 17:40:35
User entered 'No (N)'	System	24 Aug 2020 17:40:35

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:32', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '50fb3630-1c70-4725-9aad-c21b677e7e6f'	System	24 Aug 2020 17:40:35
User entered '24 Aug 2020 13:40'	System	24 Aug 2020 17:40:35

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 5'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:04:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4b924c15-1714-4ad8-9b3f-8e36d39f8af6'	System	25 Aug 2020 16:04:50
User entered 'Yes (Y)'	System	25 Aug 2020 16:04:50

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:04:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4b924c15-1714-4ad8-9b3f-8e36d39f8af6'	System	25 Aug 2020 16:04:50
User entered '98.3'	System	25 Aug 2020 16:04:50

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:04:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4b924c15-1714-4ad8-9b3f-8e36d39f8af6'	System	25 Aug 2020 16:04:50
User entered 'No (N)'	System	25 Aug 2020 16:04:50

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:04:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4b924c15-1714-4ad8-9b3f-8e36d39f8af6'	System	25 Aug 2020 16:04:50
User entered '25 Aug 2020 12:04'	System	25 Aug 2020 16:04:50

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 6'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:08:21', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e204e630-7f8e-41eb-86a0-124a92f3a0e3'	System	26 Aug 2020 17:08:55
User entered 'Yes (Y)'	System	26 Aug 2020 17:08:55

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:08:35', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e204e630-7f8e-41eb-86a0-124a92f3a0e3'	System	26 Aug 2020 17:08:55
User entered '98.4'	System	26 Aug 2020 17:08:55

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:08:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e204e630-7f8e-41eb-86a0-124a92f3a0e3'	System	26 Aug 2020 17:08:55
User entered 'No (N)'	System	26 Aug 2020 17:08:55

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:08:46', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e204e630-7f8e-41eb-86a0-124a92f3a0e3'	System	26 Aug 2020 17:08:55
User entered '26 Aug 2020 13:08'	System	26 Aug 2020 17:08:55

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 7'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:04:47', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ffab3c11-7a93-42f2-8e15-1cc57dcc99dd'	System	27 Aug 2020 17:05:20
User entered 'Yes (Y)'	System	27 Aug 2020 17:05:20

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ffab3c11-7a93-42f2-8e15-1cc57dcc99dd'	System	27 Aug 2020 17:05:20
User entered '98.5'	System	27 Aug 2020 17:05:20

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:07', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ffab3c11-7a93-42f2-8e15-1cc57dcc99dd'	System	27 Aug 2020 17:05:20
User entered 'No (N)'	System	27 Aug 2020 17:05:20

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ffab3c11-7a93-42f2-8e15-1cc57dcc99dd'	System	27 Aug 2020 17:05:20
User entered '27 Aug 2020 13:05'	System	27 Aug 2020 17:05:20

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-08-21T11:35:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd92c5b93-6a4a-4211-abee-85ea41713321'	System	21 Aug 2020 15:35:57
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 15:35:57

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:35:35', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd92c5b93-6a4a-4211-abee-85ea41713321'	System	21 Aug 2020 15:35:57
User entered 'No (N)'	System	21 Aug 2020 15:35:57

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:35:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd92c5b93-6a4a-4211-abee-85ea41713321'	System	21 Aug 2020 15:35:57
User entered 'No (N)'	System	21 Aug 2020 15:35:57

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-21T11:35:45', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd92c5b93-6a4a-4211-abee-85ea41713321'	System	21 Aug 2020 15:35:57
User entered 'None (1)'	System	21 Aug 2020 15:35:57

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:35:53', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd92c5b93-6a4a-4211-abee-85ea41713321'	System	21 Aug 2020 15:35:57
User entered '21 Aug 2020 11:35'	System	21 Aug 2020 15:35:57

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 09:55'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:25'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-08-21T16:44:30', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35cc7b71-052e-4676-b9d9-bc55d5c98ca5'	System	21 Aug 2020 20:44:49
User entered 'None (1)'	System	21 Aug 2020 20:44:49

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35cc7b71-052e-4676-b9d9-bc55d5c98ca5'	System	21 Aug 2020 20:44:49
User entered 'No (N)'	System	21 Aug 2020 20:44:49

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:37', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35cc7b71-052e-4676-b9d9-bc55d5c98ca5'	System	21 Aug 2020 20:44:49
User entered 'No (N)'	System	21 Aug 2020 20:44:49

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-21T16:44:40', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35cc7b71-052e-4676-b9d9-bc55d5c98ca5'	System	21 Aug 2020 20:44:49
User entered 'None (1)'	System	21 Aug 2020 20:44:49

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '35cc7b71-052e-4676-b9d9-bc55d5c98ca5'	System	21 Aug 2020 20:44:49
User entered '21 Aug 2020 16:44'	System	21 Aug 2020 20:44:49

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 13:20'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 2'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-08-22T16:04:45', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'cb17d1e8-3121-4f4b-b650-7cfe2db01bca'	System	22 Aug 2020 20:04:58
User entered 'None (1)'	System	22 Aug 2020 20:04:58

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'cb17d1e8-3121-4f4b-b650-7cfe2db01bca'	System	22 Aug 2020 20:04:58
User entered 'No (N)'	System	22 Aug 2020 20:04:58

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:51', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'cb17d1e8-3121-4f4b-b650-7cfe2db01bca'	System	22 Aug 2020 20:04:58
User entered 'No (N)'	System	22 Aug 2020 20:04:58

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-22T16:04:54', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'cb17d1e8-3121-4f4b-b650-7cfe2db01bca'	System	22 Aug 2020 20:04:58
User entered 'None (1)'	System	22 Aug 2020 20:04:58

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:04:57', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'cb17d1e8-3121-4f4b-b650-7cfe2db01bca'	System	22 Aug 2020 20:04:58
User entered '22 Aug 2020 16:04'	System	22 Aug 2020 20:04:58

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 3'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-08-23T12:04:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3ad6d9dc-b2c3-47a7-8c45-8e54cf95e60f'	System	23 Aug 2020 16:05:01
User entered 'None (1)'	System	23 Aug 2020 16:05:01

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:46', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3ad6d9dc-b2c3-47a7-8c45-8e54cf95e60f'	System	23 Aug 2020 16:05:01
User entered 'No (N)'	System	23 Aug 2020 16:05:01

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:50', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3ad6d9dc-b2c3-47a7-8c45-8e54cf95e60f'	System	23 Aug 2020 16:05:01
User entered 'No (N)'	System	23 Aug 2020 16:05:01

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-08-23T12:04:53', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3ad6d9dc-b2c3-47a7-8c45-8e54cf95e60f'	System	23 Aug 2020 16:05:01
User entered 'None (1)'	System	23 Aug 2020 16:05:01

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:04:56', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3ad6d9dc-b2c3-47a7-8c45-8e54cf95e60f'	System	23 Aug 2020 16:05:01
User entered '23 Aug 2020 12:04'	System	23 Aug 2020 16:05:01

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 4'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-08-24T13:40:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c6d9ec94-6301-4139-a2da-5788149d605e'	System	24 Aug 2020 17:41:08
User entered 'None (1)'	System	24 Aug 2020 17:41:08

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c6d9ec94-6301-4139-a2da-5788149d605e'	System	24 Aug 2020 17:41:08
User entered 'No (N)'	System	24 Aug 2020 17:41:08

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c6d9ec94-6301-4139-a2da-5788149d605e'	System	24 Aug 2020 17:41:08
User entered 'No (N)'	System	24 Aug 2020 17:41:08

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-24T13:40:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c6d9ec94-6301-4139-a2da-5788149d605e'	System	24 Aug 2020 17:41:08
User entered 'None (1)'	System	24 Aug 2020 17:41:08

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c6d9ec94-6301-4139-a2da-5788149d605e'	System	24 Aug 2020 17:41:08
User entered '24 Aug 2020 13:40'	System	24 Aug 2020 17:41:08

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 5'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-08-25T12:04:59', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:05:03', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered 'Yes (Y)'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db' User entered '2'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered 'Yes (Y)'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:23', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered '5'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-25T12:06:28', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered 'None (1)'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:31', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd109f95a-f5a0-4da4-8381-51e30a9e83db'	System	25 Aug 2020 16:06:36
User entered '25 Aug 2020 12:06'	System	25 Aug 2020 16:06:36

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 6'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-26T13:08:57', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:09:04', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered 'Yes (Y)'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:09:49', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0' User entered '3'	System	26 Aug 2020 17:10:28
	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:09:55', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered 'Yes (Y)'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered '3'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-08-26T13:10:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered 'None (1)'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:21', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0a72c48f-0206-46a4-8fed-a4f434c9fef0'	System	26 Aug 2020 17:10:28
User entered '26 Aug 2020 13:10'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 7'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-27T13:05:26', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff9c6954-5027-4bf0-8b40-a54101f013d1'	System	27 Aug 2020 17:06:17
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:49', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff9c6954-5027-4bf0-8b40-a54101f013d1'	System	27 Aug 2020 17:06:17
User entered 'No (N)'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:05:55', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff9c6954-5027-4bf0-8b40-a54101f013d1'	System	27 Aug 2020 17:06:17
User entered 'No (N)'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-27T13:06:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff9c6954-5027-4bf0-8b40-a54101f013d1'	System	27 Aug 2020 17:06:17
User entered 'None (1)'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff9c6954-5027-4bf0-8b40-a54101f013d1'	System	27 Aug 2020 17:06:17
User entered '27 Aug 2020 13:06'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'No interference with activity (1)'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:19', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'None (0)'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:24', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'None (0)'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:28', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'None (0)'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:31', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'None (0)'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'None (0)'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-21T11:36:40', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered 'No (N)'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T11:36:43', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebf13b5e-f600-4029-b4b0-99777cc1e234'	System	21 Aug 2020 15:36:46
User entered '21 Aug 2020 11:36'	System	21 Aug 2020 15:36:46

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 09:55'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:25'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:49', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'None (0)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'No interference with activity (1)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:56', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'None (0)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:44:59', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'None (0)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:45:02', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'None (0)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:45:04', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'None (0)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-21T16:45:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered 'No (N)'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-21T16:45:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '1614234f-b771-4219-a1c4-6225a6110261'	System	21 Aug 2020 20:45:19
User entered '21 Aug 2020 16:45'	System	21 Aug 2020 20:45:19

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 13:20'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 2'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:03', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'No interference with activity (1)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'No interference with activity (1)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'None (0)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'None (0)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'None (0)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'None (0)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-22T16:05:20', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered 'No (N)'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-22T16:05:23', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'd01732d2-27d9-4e4a-b5b9-09b837f38a6e'	System	22 Aug 2020 20:05:26
User entered '22 Aug 2020 16:05'	System	22 Aug 2020 20:05:26

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 3'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:03', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:13', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:15', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:17', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'None (0)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-23T12:05:20', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered 'No (N)'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-23T12:05:22', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '4d74408b-e48a-46c4-83aa-0bec390ad9c9'	System	23 Aug 2020 16:05:27
User entered '23 Aug 2020 12:05'	System	23 Aug 2020 16:05:27

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 4'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:40:58', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:04', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:13', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'None (0)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-24T13:41:18', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered 'No (N)'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-24T13:41:22', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '0d410726-db4a-4906-8e0c-84a0f2931af8'	System	24 Aug 2020 17:41:25
User entered '24 Aug 2020 13:41'	System	24 Aug 2020 17:41:25

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 5'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:42', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:45', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:51', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:06:54', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'None (0)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-25T12:06:57', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered 'No (N)'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-25T12:07:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '96e3f228-9c09-4a9c-b605-3ad3134b5683'	System	25 Aug 2020 16:07:06
User entered '25 Aug 2020 12:07'	System	25 Aug 2020 16:07:06

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 6'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:31', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'No interference with activity (1)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'None (0)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'None (0)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:10:54', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'None (0)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:11:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'None (0)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:11:05', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'None (0)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-26T13:11:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered 'No (N)'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-26T13:11:20', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '70649d1a-50df-437d-abd7-a485ce84fd59'	System	26 Aug 2020 17:11:23
User entered '26 Aug 2020 13:11'	System	26 Aug 2020 17:11:23

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Aug 2020 13:26:24
User entered 'Day 7'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:20', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:30', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:43', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'None (0)'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-08-27T13:06:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered 'No (N)'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-08-27T13:06:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2d9a04f5-3003-42bf-8197-1caac000a017'	System	27 Aug 2020 17:06:56
User entered '27 Aug 2020 13:06'	System	27 Aug 2020 17:06:56

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 13:26:24

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 17:10:28
User entered 'Day 8'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 17:06:17
User entered 'Day 9'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 17:10:28
User entered 'Day 8'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 17:10:28

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Aug 2020 17:06:17
User entered 'Day 9'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 17:06:17

US3522269

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 17:06:17

US3522269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 18:07:36

US3522269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 18:07:36

US3522269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	28 Aug 2020 18:07:36

US3522269

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'attempted to reach patient with no success. will attempt at later time.'	(b) (4), (b) (6)	28 Aug 2020 18:07:36

US3522269

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:10:38

US3522269

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:10:38

US3522269

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:12:58

US3522269

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	10 Nov 2020 17:53:44
User entered '4 Sep 2020'	Tyler Prentiss (b) (4)	04 Sep 2020 18:12:58

US3522269

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:12:58

US3522269

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Contact not made; voicemail left'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:12:58

US3522269

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tyler Prentiss (b) (4) (b) (4)	04 Sep 2020 18:13:04

US3522269

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 18:13:04

US3522269

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alayna Wilder (b) (4) (b) (4)	11 Sep 2020 15:25:21

US3522269

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 05:56:09
User entered '16 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4)	16 Sep 2020 21:53:02
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Yaman Ahmed (b) (4)	15 Sep 2020 21:15:28
answered with 'multiple contact attempts; see audit history' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Sep 2020 21:15:16
User entered '15 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4)	15 Sep 2020 21:15:16
User entered '11 Sep 2020'	Alayna Wilder (b) (4)	11 Sep 2020 15:25:21
	(b) (4)	

US3522269

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Alayna Wilder (b) (4) (b) (4)	11 Sep 2020 15:25:21

US3522269

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered '1ST ATTEMPT 11 SEP 2020; 2ND ATTEMPT 15 SEP 2020; 3rd attempt 16 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	16 Sep 2020 21:53:02
User entered '1st attempt 11 Sep 2020; 2nd attempt 15 Sep 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	15 Sep 2020 21:15:16
User entered 'left vm'	Alayna Wilder (b) (4) (b) (4)	11 Sep 2020 15:25:21

US3522269

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:58:34

US3522269

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 17:58:34

US3522269

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:58:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:58:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Sep 2020 17:58:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:33:08

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	22 Sep 2020 17:58:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	29 Sep 2020 15:18:52
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	22 Sep 2020 18:50:24
User entered '13:47'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '22 Sep 2020 13:47'	System	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'Temporal'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '86'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '108'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '65'	(b) (4), (b) (6)	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:33:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 17:59:50

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '14:45' reason for change: New Information	(b) (4), (b) (6)	15 Oct 2020 18:51:45
User entered '14:15'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '22 Sep 2020 14:45'	System	15 Oct 2020 18:51:45
User entered '22 Sep 2020 14:15'	System	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'TEMPORAL'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '84'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '105'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:33:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Sep 2020 18:53:44

US3522269

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 17:59:59

US3522269

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:33:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 17:59:59

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Collection date](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

[Collection time](#)

Audit	User	Time (GMT)
User entered '13:32'	(b) (4), (b) (6)	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '22 Sep 2020 13:32'	System	22 Sep 2020 18:01:26

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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)	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '14:15' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Sep 2020 15:18:52
User entered '13:15'	(b) (4), (b) (6)	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '22 Sep 2020 14:15'	System	29 Sep 2020 15:18:52
User entered '22 Sep 2020 13:15'	System	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 18:50:24

US3522269

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:21:29

US3522269

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:21:29

US3522269

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '14:10'	(b) (4), (b) (6)	22 Sep 2020 18:21:29

US3522269

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '22 Sep 2020 14:10'	System	22 Sep 2020 18:21:29

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:33:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '14:12'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '22 Sep 2020 14:12'	System	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:08

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 18:21:45

US3522269

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:21:52

US3522269

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:21:52

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:50:43', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '7de68ad1-555f-4eed-81d0-04f8b8f52d20'	System	22 Sep 2020 18:51:05
User entered 'Yes (Y)'	System	22 Sep 2020 18:51:05

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:50:50', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '7de68ad1-555f-4eed-81d0-04f8b8f52d20'	System	22 Sep 2020 18:51:05
User entered '98.2'	System	22 Sep 2020 18:51:05

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:50:55', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '7de68ad1-555f-4eed-81d0-04f8b8f52d20'	System	22 Sep 2020 18:51:05
User entered 'No (N)'	System	22 Sep 2020 18:51:05

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '7de68ad1-555f-4eed-81d0-04f8b8f52d20'	System	22 Sep 2020 18:51:05
User entered '22 Sep 2020 14:51'	System	22 Sep 2020 18:51:05

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 13:35'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 16:05'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:57:02', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c7896e7b-b432-425d-b48d-023586a1283f'	System	22 Sep 2020 22:58:02
User entered 'Yes (Y)'	System	22 Sep 2020 22:58:02

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:57:49', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c7896e7b-b432-425d-b48d-023586a1283f'	System	22 Sep 2020 22:58:02
User entered '99.0'	System	22 Sep 2020 22:58:02

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:57:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c7896e7b-b432-425d-b48d-023586a1283f'	System	22 Sep 2020 22:58:02
User entered 'No (N)'	System	22 Sep 2020 22:58:02

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:57:59', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c7896e7b-b432-425d-b48d-023586a1283f'	System	22 Sep 2020 22:58:02
User entered '22 Sep 2020 18:57'	System	22 Sep 2020 22:58:02

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 17:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 2'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:26:08', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e854e9ec-88be-4917-9ff7-41a280e3ed2b'	System	23 Sep 2020 16:27:14
User entered 'Yes (Y)'	System	23 Sep 2020 16:27:14

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:03', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e854e9ec-88be-4917-9ff7-41a280e3ed2b'	System	23 Sep 2020 16:27:14
User entered '98.3'	System	23 Sep 2020 16:27:14

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e854e9ec-88be-4917-9ff7-41a280e3ed2b'	System	23 Sep 2020 16:27:14
User entered 'No (N)'	System	23 Sep 2020 16:27:14

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'e854e9ec-88be-4917-9ff7-41a280e3ed2b'	System	23 Sep 2020 16:27:14
User entered '23 Sep 2020 12:27'	System	23 Sep 2020 16:27:14

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 3'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:57:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '6666f69f-21e1-402b-bbfc-2cd561f0458f'	System	24 Sep 2020 16:57:58
User entered 'Yes (Y)'	System	24 Sep 2020 16:57:58

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:57:47', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '6666f69f-21e1-402b-bbfc-2cd561f0458f'	System	24 Sep 2020 16:57:58
User entered '98.8'	System	24 Sep 2020 16:57:58

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:57:50', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '6666f69f-21e1-402b-bbfc-2cd561f0458f'	System	24 Sep 2020 16:57:58
User entered 'No (N)'	System	24 Sep 2020 16:57:58

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:57:53', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '6666f69f-21e1-402b-bbfc-2cd561f0458f' User entered '24 Sep 2020 12:57'	System	24 Sep 2020 16:57:58
	System	24 Sep 2020 16:57:58

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 4'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:36:50', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0d62dfa-a3c6-40a9-a5a6-2c0f4c034585'	System	25 Sep 2020 16:38:19
User entered 'Yes (Y)'	System	25 Sep 2020 16:38:19

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0d62dfa-a3c6-40a9-a5a6-2c0f4c034585'	System	25 Sep 2020 16:38:19
User entered '98.8'	System	25 Sep 2020 16:38:19

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:12', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0d62dfa-a3c6-40a9-a5a6-2c0f4c034585'	System	25 Sep 2020 16:38:19
User entered 'No (N)'	System	25 Sep 2020 16:38:19

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:15', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0d62dfa-a3c6-40a9-a5a6-2c0f4c034585'	System	25 Sep 2020 16:38:19
User entered '25 Sep 2020 12:38'	System	25 Sep 2020 16:38:19

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 5'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:32', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '42e6228e-b2bd-4703-87bf-af3120a27191'	System	26 Sep 2020 16:05:47
User entered 'Yes (Y)'	System	26 Sep 2020 16:05:47

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '42e6228e-b2bd-4703-87bf-af3120a27191'	System	26 Sep 2020 16:05:47
User entered '98.7'	System	26 Sep 2020 16:05:47

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '42e6228e-b2bd-4703-87bf-af3120a27191'	System	26 Sep 2020 16:05:47
User entered 'No (N)'	System	26 Sep 2020 16:05:47

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '42e6228e-b2bd-4703-87bf-af3120a27191'	System	26 Sep 2020 16:05:47
User entered '26 Sep 2020 12:05'	System	26 Sep 2020 16:05:47

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 6'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebea2675-61fd-4dd7-896e-a7140dab6b60'	System	27 Sep 2020 16:36:48
User entered 'Yes (Y)'	System	27 Sep 2020 16:36:48

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:37', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebea2675-61fd-4dd7-896e-a7140dab6b60'	System	27 Sep 2020 16:36:48
User entered '98.4'	System	27 Sep 2020 16:36:48

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebea2675-61fd-4dd7-896e-a7140dab6b60'	System	27 Sep 2020 16:36:48
User entered 'No (N)'	System	27 Sep 2020 16:36:48

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ebea2675-61fd-4dd7-896e-a7140dab6b60'	System	27 Sep 2020 16:36:48
User entered '27 Sep 2020 12:36'	System	27 Sep 2020 16:36:48

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 7'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:03:51', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '8905fa29-b8a2-41ae-bbc4-8ee833dc8a80'	System	28 Sep 2020 16:04:59
User entered 'Yes (Y)'	System	28 Sep 2020 16:04:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:31', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '8905fa29-b8a2-41ae-bbc4-8ee833dc8a80'	System	28 Sep 2020 16:04:59
User entered '98.6'	System	28 Sep 2020 16:04:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:33', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '8905fa29-b8a2-41ae-bbc4-8ee833dc8a80'	System	28 Sep 2020 16:04:59
User entered 'No (N)'	System	28 Sep 2020 16:04:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:37', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '8905fa29-b8a2-41ae-bbc4-8ee833dc8a80'	System	28 Sep 2020 16:04:59
User entered '28 Sep 2020 12:04'	System	28 Sep 2020 16:04:59

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-22T14:51:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '26b1b6c3-82b5-44dd-b268-d17dd742faf1'	System	22 Sep 2020 18:51:35
User entered 'None (1)'	System	22 Sep 2020 18:51:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:15', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '26b1b6c3-82b5-44dd-b268-d17dd742faf1'	System	22 Sep 2020 18:51:35
User entered 'No (N)'	System	22 Sep 2020 18:51:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:19', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '26b1b6c3-82b5-44dd-b268-d17dd742faf1'	System	22 Sep 2020 18:51:35
User entered 'No (N)'	System	22 Sep 2020 18:51:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-09-22T14:51:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '26b1b6c3-82b5-44dd-b268-d17dd742faf1'	System	22 Sep 2020 18:51:35
User entered 'None (1)'	System	22 Sep 2020 18:51:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:28', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '26b1b6c3-82b5-44dd-b268-d17dd742faf1'	System	22 Sep 2020 18:51:35
User entered '22 Sep 2020 14:51'	System	22 Sep 2020 18:51:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 13:35'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 16:05'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-22T18:58:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '29f7d08f-4dbe-470f-9d26-1ba1a2580809'	System	22 Sep 2020 22:58:22
User entered 'None (1)'	System	22 Sep 2020 22:58:22

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '29f7d08f-4dbe-470f-9d26-1ba1a2580809'	System	22 Sep 2020 22:58:22
User entered 'No (N)'	System	22 Sep 2020 22:58:22

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:12', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '29f7d08f-4dbe-470f-9d26-1ba1a2580809'	System	22 Sep 2020 22:58:22
User entered 'No (N)'	System	22 Sep 2020 22:58:22

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-22T18:58:15', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '29f7d08f-4dbe-470f-9d26-1ba1a2580809'	System	22 Sep 2020 22:58:22
User entered 'None (1)'	System	22 Sep 2020 22:58:22

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:18', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '29f7d08f-4dbe-470f-9d26-1ba1a2580809'	System	22 Sep 2020 22:58:22
User entered '22 Sep 2020 18:58'	System	22 Sep 2020 22:58:22

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 17:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 2'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-09-23T12:27:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '16d70a86-dd85-423e-8ee5-4fe36c168997'	System	23 Sep 2020 16:27:31
User entered 'None (1)'	System	23 Sep 2020 16:27:31

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:19', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '16d70a86-dd85-423e-8ee5-4fe36c168997'	System	23 Sep 2020 16:27:31
User entered 'No (N)'	System	23 Sep 2020 16:27:31

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:21', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '16d70a86-dd85-423e-8ee5-4fe36c168997'	System	23 Sep 2020 16:27:31
User entered 'No (N)'	System	23 Sep 2020 16:27:31

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-09-23T12:27:23', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '16d70a86-dd85-423e-8ee5-4fe36c168997'	System	23 Sep 2020 16:27:31
User entered 'None (1)'	System	23 Sep 2020 16:27:31

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:27', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '16d70a86-dd85-423e-8ee5-4fe36c168997'	System	23 Sep 2020 16:27:31
User entered '23 Sep 2020 12:27'	System	23 Sep 2020 16:27:31

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 3'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-09-24T12:57:57', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '5a015f2b-ec61-4b5c-87ec-fe0a0781dc5e'	System	24 Sep 2020 16:58:10
User entered 'None (1)'	System	24 Sep 2020 16:58:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '5a015f2b-ec61-4b5c-87ec-fe0a0781dc5e'	System	24 Sep 2020 16:58:10
User entered 'No (N)'	System	24 Sep 2020 16:58:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:01', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '5a015f2b-ec61-4b5c-87ec-fe0a0781dc5e'	System	24 Sep 2020 16:58:10
User entered 'No (N)'	System	24 Sep 2020 16:58:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-09-24T12:58:03', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '5a015f2b-ec61-4b5c-87ec-fe0a0781dc5e'	System	24 Sep 2020 16:58:10
User entered 'None (1)'	System	24 Sep 2020 16:58:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '5a015f2b-ec61-4b5c-87ec-fe0a0781dc5e'	System	24 Sep 2020 16:58:10
User entered '24 Sep 2020 12:58'	System	24 Sep 2020 16:58:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 4'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-09-25T12:38:19', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '15a1af6e-b2a8-4bf9-b851-5b0a31d2fcd7'	System	25 Sep 2020 16:38:35
User entered 'None (1)'	System	25 Sep 2020 16:38:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:21', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '15a1af6e-b2a8-4bf9-b851-5b0a31d2fcd7'	System	25 Sep 2020 16:38:35
User entered 'No (N)'	System	25 Sep 2020 16:38:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:23', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '15a1af6e-b2a8-4bf9-b851-5b0a31d2fcd7'	System	25 Sep 2020 16:38:35
User entered 'No (N)'	System	25 Sep 2020 16:38:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-25T12:38:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '15a1af6e-b2a8-4bf9-b851-5b0a31d2fcd7'	System	25 Sep 2020 16:38:35
User entered 'None (1)'	System	25 Sep 2020 16:38:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:28', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '15a1af6e-b2a8-4bf9-b851-5b0a31d2fcd7'	System	25 Sep 2020 16:38:35
User entered '25 Sep 2020 12:38'	System	25 Sep 2020 16:38:35

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 5'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-26T12:05:48', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '114815b5-51de-43ef-adf6-3fb3bf476a17'	System	26 Sep 2020 16:05:59
User entered 'None (1)'	System	26 Sep 2020 16:05:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:50', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '114815b5-51de-43ef-adf6-3fb3bf476a17'	System	26 Sep 2020 16:05:59
User entered 'No (N)'	System	26 Sep 2020 16:05:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '114815b5-51de-43ef-adf6-3fb3bf476a17'	System	26 Sep 2020 16:05:59
User entered 'No (N)'	System	26 Sep 2020 16:05:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-26T12:05:54', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '114815b5-51de-43ef-adf6-3fb3bf476a17'	System	26 Sep 2020 16:05:59
User entered 'None (1)'	System	26 Sep 2020 16:05:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:05:56', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '114815b5-51de-43ef-adf6-3fb3bf476a17'	System	26 Sep 2020 16:05:59
User entered '26 Sep 2020 12:05'	System	26 Sep 2020 16:05:59

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 6'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-09-27T12:36:56', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '61a188cd-ca30-48bb-8fc4-098d3d5748b9'	System	27 Sep 2020 16:37:10
User entered 'None (1)'	System	27 Sep 2020 16:37:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:36:58', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '61a188cd-ca30-48bb-8fc4-098d3d5748b9'	System	27 Sep 2020 16:37:10
User entered 'No (N)'	System	27 Sep 2020 16:37:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '61a188cd-ca30-48bb-8fc4-098d3d5748b9'	System	27 Sep 2020 16:37:10
User entered 'No (N)'	System	27 Sep 2020 16:37:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-27T12:37:02', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '61a188cd-ca30-48bb-8fc4-098d3d5748b9'	System	27 Sep 2020 16:37:10
User entered 'None (1)'	System	27 Sep 2020 16:37:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:05', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '61a188cd-ca30-48bb-8fc4-098d3d5748b9'	System	27 Sep 2020 16:37:10
User entered '27 Sep 2020 12:37'	System	27 Sep 2020 16:37:10

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 7'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-09-28T12:04:43', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '118dd802-5985-4cf9-8a78-36d056939dcf'	System	28 Sep 2020 16:05:12
User entered 'None (1)'	System	28 Sep 2020 16:05:12

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:45', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '118dd802-5985-4cf9-8a78-36d056939dcf'	System	28 Sep 2020 16:05:12
User entered 'No (N)'	System	28 Sep 2020 16:05:12

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:46', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '118dd802-5985-4cf9-8a78-36d056939dcf'	System	28 Sep 2020 16:05:12
User entered 'No (N)'	System	28 Sep 2020 16:05:12

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

[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 (3184377762f6b62a)', Time: '2020-09-28T12:04:49', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '118dd802-5985-4cf9-8a78-36d056939dcf'	System	28 Sep 2020 16:05:12
User entered 'None (1)'	System	28 Sep 2020 16:05:12

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:51', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '118dd802-5985-4cf9-8a78-36d056939dcf'	System	28 Sep 2020 16:05:12
User entered '28 Sep 2020 12:04'	System	28 Sep 2020 16:05:12

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:36', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:43', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:45', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'None (0)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-22T14:51:52', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered 'No (N)'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T14:51:55', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'b78a039c-e8e0-48c3-9cee-c7e289cfdac1'	System	22 Sep 2020 18:52:01
User entered '22 Sep 2020 14:51'	System	22 Sep 2020 18:52:01

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 13:35'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 16:05'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'No interference with activity (1)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:29', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'No interference with activity (1)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:32', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'None (0)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'None (0)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:36', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'None (0)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'None (0)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-22T18:58:42', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered 'No (N)'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-22T18:58:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '2f2b70f7-b15c-4894-b4a8-1883d178ea64'	System	22 Sep 2020 22:58:49
User entered '22 Sep 2020 18:58'	System	22 Sep 2020 22:58:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 17:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 2'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:31', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:33', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:36', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:39', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:41', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'None (0)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-23T12:27:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered 'No (N)'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-23T12:27:46', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ff94990d-3046-45ee-b149-6eeef0fd1f3a'	System	23 Sep 2020 16:27:50
User entered '23 Sep 2020 12:27'	System	23 Sep 2020 16:27:50

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 3'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:12', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:16', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:18', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:20', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'None (0)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-24T12:58:22', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered 'No (N)'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-24T12:58:25', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'bd788de3-6cc8-4963-b52a-baa9d567aeab'	System	24 Sep 2020 16:58:33
User entered '24 Sep 2020 12:58'	System	24 Sep 2020 16:58:33

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 4'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:32', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:34', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:36', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:37', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:38', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:40', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'None (0)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-25T12:38:42', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered 'No (N)'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-25T12:38:44', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'c0629f09-04db-4649-9f4d-d5c83961d64b'	System	25 Sep 2020 16:38:49
User entered '25 Sep 2020 12:38'	System	25 Sep 2020 16:38:49

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 5'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:02', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:04', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:06', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:08', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'None (0)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-26T12:06:12', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered 'No (N)'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-26T12:06:14', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '3b47eb66-766a-493a-991a-51840db48168'	System	26 Sep 2020 16:06:20
User entered '26 Sep 2020 12:06'	System	26 Sep 2020 16:06:20

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 6'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:10', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:11', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:13', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f' User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:15', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:17', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:19', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'None (0)'	System	27 Sep 2020 16:37:28

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-27T12:37:22', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f'	System	27 Sep 2020 16:37:28
User entered 'No (N)'	System	27 Sep 2020 16:37:28

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-27T12:37:24', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: 'ad72ddf9-d8f6-42c4-b141-03d54692512f' User entered '27 Sep 2020 12:37'	System	27 Sep 2020 16:37:28
	System	27 Sep 2020 16:37:28

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Sep 2020 18:50:24
User entered 'Day 7'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:55', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:57', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:04:58', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:05:00', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:05:02', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:05:04', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'None (0)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

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 (3184377762f6b62a)', Time: '2020-09-28T12:05:07', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered 'No (N)'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3184377762f6b62a)', Time: '2020-09-28T12:05:09', User OID: 'PatientReportedOutcome (US3522269)', ODM File OID: '632908c4-2e08-42b2-92eb-524ed76ab964'	System	28 Sep 2020 16:05:19
User entered '28 Sep 2020 12:05'	System	28 Sep 2020 16:05:19

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 18:50:24

US3522269

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:33:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 18:50:24

US3522269

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:16:19

US3522269

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 15:16:19

US3522269

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Sep 2020 15:16:19

US3522269

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 15:16:19

US3522269

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 15:16:24

US3522269

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Sep 2020 15:16:24

US3522269

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	06 Oct 2020 14:19:06

US3522269

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020' reason for change: Data Entry Error	Kristin Eis (b) (4)	07 Oct 2020 14:49:49
User entered '6 Oct 2020'	Alandra White (b) (4)	06 Oct 2020 14:19:06

US3522269

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:08:37
User entered 'Contact Not Made (CONTACT NOT MADE)'	Alandra White (b) (4) (b) (4)	06 Oct 2020 14:19:06

US3522269

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Flu Vaccine received 05 Oct 2020. No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk' reason for change: New Information	Yaman Ahmed (b) (4)	07 Oct 2020 16:08:37
User entered 'Call attempted with no answer, left voicemail.'	Alandra White (b) (4)	06 Oct 2020 14:19:06

US3522269

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kristin Eis (b) (4) [REDACTED]	07 Oct 2020 14:52:34

US3522269

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 14:52:34

US3522269

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:18:14

US3522269

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 15:18:14

US3522269

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Oct 2020 15:18:14

US3522269

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:33:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:18:14

US3522269

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:18:18

US3522269

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:33:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 15:18:18

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '18 Oct 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '22 Oct 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '25 Oct 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '29 Oct 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '01 Nov 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '05 Nov 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '08 Nov 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '12 Nov 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '15 Nov 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '19 Nov 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:23:17

US3522269

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:33:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:23:17
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:23:17

US3522269

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:33:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:59
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 18:40:58

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:52:27
User entered 'USA-US131-2020-mRNA-1273-P301000005'	System	23 Sep 2020 11:52:16
User entered 'New'	(b) (4), (b) (6)	23 Sep 2020 11:52:16

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' answered with 'Not in for an illness visit. Did not inform until arriving at Visit 2. Swab at visit 2 was negative' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:10:36
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the events of nausea, abdominal pain, and vomiting ' answered with 'Unknown. See queries further down for more detail' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:10:15
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:56
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate). ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 06:48:32
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the events of nausea, abdominal pain, and vomiting ' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:41:31
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the events.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:40:46
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the events.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:37:25
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 18:58:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 18:58:49
Data point term sent to Coder	System	01 Oct 2020 18:58:04
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 18:57:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 18:57:54
User closed query 'For coding purposes, please split NAUSEA/VOMITING into separate entries' (Site from System).	System	01 Oct 2020 18:57:04
Query 'For coding purposes, please split NAUSEA/VOMITING into separate entries' answered with 'split' (Site from System).	Sharon Mathys (b) (4)	01 Oct 2020 18:57:04
Data point term sent to Coder	System	01 Oct 2020 18:57:00
User entered 'NAUSEA' reason for change: Data Entry Error	Sharon Mathys (b) (4)	01 Oct 2020 18:56:59
User opened query 'For coding purposes, please split NAUSEA/VOMITING into separate entries' (Site from System).	Coder Import (b) (4)	29 Sep 2020 14:29:36
Data point term sent to Coder	System	22 Sep 2020 20:18:22
User entered 'Nausea/Vomiting'	Sharon Mathys (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' answered with 'updated' (Site from DM). DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:09:55
	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:09:47
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:09:47
User opened query 'Per DM CLR: Note, solicited reactions are only reported as AE if it meets AE reporting criteria. This AE started after Day 7, review if this is considered as unsolicited event per protocol. If yes, update this field to No. Else, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 09:25:59
	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:28:16
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '7 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '15 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Con procedure was entered as she mentioned procedures being done and did not elaborate. See queries further down for answer.' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:11:03
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6) (b) (4)	02 Nov 2020 09:26:08
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	08 Oct 2020 20:12:34
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'None (NONE)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'In error' (Site from DM). DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:15:43
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:15:21
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 07:05:01
User entered '1'	Sharon Mathys (b) (4) (b) (4)	08 Oct 2020 20:12:34
		22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Participant has gone no contact with the study on request of a release form for hospital records in Canada. Certified letter has been sent after 5 attempts at contact. Participant no showed Visit 3 as well. It is anticipated that participant will be withdrawn from the study and no further information can be obtained.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:15:29
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.' answered with 'Participant has gone no contact with the study on request of a release form for hospital records in Canada. Certified letter has been sent after 5 attempts at contact. Participant no showed Visit 3 as well. It is anticipated that participant will be withdrawn from the study and no further information can be obtained.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:15:26
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'No medical history given to site staff prior to onset and site staff was not given access to prior medical records.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:11:31
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) (b) (4)	09 Oct 2020 14:38:25
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)	09 Oct 2020 14:37:59

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:37:42
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:34
User entered 'Nausea onset 7-Sep-2020, gradual and got worse over the following days, vomiting and abdominal pain started 8-Sep-2020, and got worse the next few days. She drove herself to the Windsor Regional Hospital on 11-Sep-2020 or 12-Sep-2020, she could not remember the date. At the time, the vomiting was severe, she vomited any time that she tried to eat something, at least 5-10 times that day, and was dry heaving at several other points	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:17:45

The hospital was concerned about gallstones. She had an ultrasound 11-Sep-2020 or 12-Sep-2020 and then she had to wait to get the MRCP until 12-Sep-2020 or 13-Sep-2020, but the results came back showing no gallstones. They did find that she had dilated bile ducts. She also had a low potassium and magnesium from the vomiting. She was given IV replacement. Over the next day or two, her vomiting and nausea resolved, and liquid then solid food was reintroduced and tolerated ok. She was discharged 16-Sep-2020. They did not discharge her on any chronic or ongoing medications. The nausea and vomiting had completely resolved at that point.

Zofran 1 tab PO as needed, start date 9/12/20- stop date 9/14/20 (approximate dates)

Morphine 1 tab PO as needed, start date 9/12/20- stop date 9/13/20 (approximate dates)

Protonix, 1 tab PO daily, start date 9/12/20- stop date 9/16/20 (approximate dates)

Potassium, IV, as needed, start date 9/12/20- stop date 9/13/20 (approximate dates)

Magnesium IV, as needed, start date 9/12/20- stop date 9/13/20 (approximate dates)

Calcium 1 tab PO daily, start date 9/14/20- stop date 9/16/20 (approximate dates)

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:33:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 20:17:45

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:52:53
User entered 'USA-US131-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	23 Sep 2020 11:52:49

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:32:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:32:43
Data point term sent to Coder	System	22 Sep 2020 20:31:47
User entered 'Abdominal Pain'	Sharon Mathys (b) (4)	22 Sep 2020 20:30:50
	(b) (4)	

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '8 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '15 Sep 2020' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Sep 2020 20:32:12
User entered '16 Sep 2020'	Sharon Mathys (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'None (NONE)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'in error' (Site from DM). DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:16:09
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:16:02
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 07:05:12
User entered '1'	Sharon Mathys (b) (4) (b) (4)	08 Oct 2020 20:12:37
		22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:12:37
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 20:31:36
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	22 Sep 2020 20:31:36
User entered 'vomiting and abdominal pain started 8-Sep-2020, and got worse the next few days. She drove herself to the Windsor Regional Hospital on 11-Sep-2020 or 12-Sep-2020, she could not remember the date. At the time, the vomiting was severe, she vomited any time that she tried to eat something, at least 5-10 times that day, and was dry heaving at several other points	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:31:36
The hospital was concerned about gallstones. She had an ultrasound 11-Sep-2020 or 12-Sep-2020 and then she had to wait to get the MRCP until 12-Sep-2020 or 13-Sep-2020, but the results came back showing no gallstones. They did find that she had dilated bile ducts. She also had a low potassium and magnesium from the vomiting. She was given IV replacement. Over the next day or two, her vomiting and nausea resolved, and liquid then solid food was reintroduced and tolerated ok. She was discharged 16-Sep-2020. They did not discharge her on any chronic or ongoing medications. The nausea and vomiting had completely resolved at that point.' reason for change: Data Entry Error		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Sep 2020 20:30:50
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:33:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Sep 2020 20:30:50

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:49:54
User entered 'USA-US131-2020-mRNA-1273-P301000005'	(b) (4), (b) (6)	02 Oct 2020 12:49:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' answered with 'Was not informed of this symptom by the participant until at Visit 2. At that time was healthy and an NP swab was taken for the visit and came back negative' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	24 Nov 2020 21:17:31
User opened query 'Per MM: The AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' ' (Site from DM).	(b) (4), (b) (6) (b) (4)	20 Oct 2020 10:38:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	08 Oct 2020 20:13:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Vomiting, LLT: Vomiting - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:57:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:57:53
Data point term sent to Coder	System	01 Oct 2020 18:56:56
User entered 'VOMITING'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '8 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered empty.	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '15 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered empty.	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Grade 4 (Grade 4)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4)	01 Oct 2020 18:56:48
	(b) (4)	

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '1'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '12 Sep 2020'	Sharon Mathys (b) (4)	01 Oct 2020 18:56:48
	(b) (4)	

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered empty.	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Not Related (NOT RELATED)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'None (NONE)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '1'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered '0'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24
User entered empty.	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:13:24

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Narrative](#)

Audit	User	Time (GMT)
User entered 'VOMITING AND ABDOMINAL PAIN STARTED 8-SEP-2020, AND GOT WORSE THE NEXT FEW DAYS. SHE DROVE HERSELF TO THE WINDSOR REGIONAL HOSPITAL ON 11-SEP-2020 OR 12-SEP-2020, SHE COULD NOT REMEMBER THE DATE. AT THE TIME, THE VOMITING WAS SEVERE, SHE VOMITED ANY TIME THAT SHE TRIED TO EAT SOMETHING, AT LEAST 5-10 TIMES THAT DAY, AND WAS DRY HEAVING AT SEVERAL OTHER POINTS THE HOSPITAL WAS CONCERNED ABOUT GALLSTONES. SHE HAD AN ULTRASOUND 11-SEP-2020 OR 12-SEP-2020 AND THEN SHE HAD TO WAIT TO GET THE MRCP UNTIL 12-SEP-2020 OR 13-SEP-2020, BUT THE RESULTS CAME BACK SHOWING NO GALLSTONES. THEY DID FIND THAT SHE HAD DILATED BILE DUCTS. SHE ALSO HAD A LOW POTASSIUM AND MAGNESIUM FROM THE VOMITING. SHE WAS GIVEN IV REPLACEMENT. OVER THE NEXT DAY OR TWO, HER VOMITING AND NAUSEA RESOLVED, AND LIQUID THEN SOLID FOOD WAS REINTRODUCED AND TOLERATED OK.SHE WAS DISCHARGED 16-SEP-2020. THEY DID NOT DISCHARGE HER ON ANY CHRONIC OR ONGOING MEDICATIONS. THE NAUSEA AND VOMITING HAD COMPLETELY RESOLVED AT THAT POINT. ZOFRAN 1 TAB PO AS NEEDED, START DATE 9/12/20- STOP DATE 9/14/20 (APPROXIMATE DATES) MORPHINE 1 TAB PO AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES) PROTONIX, 1 TAB PO DAILY, START DATE 9/12/20- STOP DATE 9/16/20 (APPROXIMATE DATES) POTASSIUM, IV, AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES) MAGNESIUM IV, AS NEEDED, START DATE 9/12/20- STOP DATE 9/13/20 (APPROXIMATE DATES) CALCIUM 1 TAB	Sharon Mathys (b) (4) (b) (4)	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Narrative](#)

Audit	User	Time (GMT)
PO DAILY, START DATE 9/14/20- STOP DATE 9/16/20 (APPROXIMATE DATES)		

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 18:56:48

US3522269

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:33:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Oct 2020 18:56:48

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:33:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:19:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:20:19

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:24:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 20:24:51
Data point term sent to Coder	System	22 Sep 2020 20:23:31
User entered 'Zofran'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:23:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 20:23:10
User entered 'No (N)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Sep 2020 20:23:10
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:23:01
User entered empty.	Sharon Mathys (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered 'Nausea'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:01:43
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:10:37
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:10:29
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:11:32
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:10:29
User entered 'tablet (TABLET)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User entered '14 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:17:48
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:02:49
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:10:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:10:29
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:11:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	22 Sep 2020 20:29:19
User entered 'No (N)'	Sharon Mathys (b) (4)	22 Sep 2020 20:23:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:23:01

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:01:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 11:01:32
Data point term sent to Coder	System	05 Nov 2020 18:14:53
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 18:13:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 05:51:48
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 Sep 2020 05:51:48
Data point term sent to Coder	System	22 Sep 2020 20:26:38
User entered 'Morphine'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:56:19
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:14:00
User entered 'abdominal PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:13:56
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:12:02
User entered 'Pain'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:02:04
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:11:35
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:11:30
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:12:10
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:11:30
User entered 'tablet (TABLET)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered '13 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:02
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:25:43

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:50:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 05:50:16
Data point term sent to Coder	System	07 Oct 2020 14:52:40
User closed query 'CDM-Coding: The trade name PROTONIX 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.	System	07 Oct 2020 14:52:26
' (Site from System).		
Query 'CDM-Coding: The trade name PROTONIX 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.	Kristin Eis (b) (4)	07 Oct 2020 14:52:26
' answered with 'corrected' (Site from System).		
User entered 'pantoprazole' reason for change: Data Entry Error	Kristin Eis (b) (4)	07 Oct 2020 14:52:18
User opened query 'CDM-Coding: The trade name PROTONIX 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.	Coder Import (b) (4) (b) (4)	23 Sep 2020 10:04:45
' (Site from System).		
Data point term sent to Coder	System	22 Sep 2020 20:27:39
User entered 'Protonix'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'Nausea'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:02:15
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:15:27
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:15:02
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:12:48
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:15:02
User entered 'tablet (TABLET)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:26
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:00:18
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:15:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 18:15:08
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of NAUSEA in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:13:27
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 20:27:24

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
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)	23 Sep 2020 09:43:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 09:43:50
Data point term sent to Coder	System	22 Sep 2020 20:40:03
User entered 'POTASSIUM IV' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:39:07
Data point term sent to Coder	System	22 Sep 2020 20:35:52
User entered 'Potassium'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'Electrolyte replacement for vomiting'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'unknown'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'IV bag'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User entered '13 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:49
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:14:26
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'mistake' (Site from DM).	Sharon Mathys (b) (4)	30 Oct 2020 15:32:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	30 Oct 2020 15:32:34
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:14:22
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:35:50

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
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)	23 Sep 2020 05:48:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 05:48:57
Data point term sent to Coder	System	22 Sep 2020 20:37:54
User entered 'Magnesium IV'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'ELECTROLYTE REPLACEMENT For VOMITING' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:43
User entered 'Electrolyte Replacement post Vomiting'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'unknown'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'Other (OTHER)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'IV drip'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'as needed (PRN)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered '12 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User entered '13 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:52
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:14:34
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'mistake' (Site from DM).	Sharon Mathys (b) (4)	30 Oct 2020 15:33:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	30 Oct 2020 15:32:58
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:14:58
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:37:12

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
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)	22 Sep 2020 21:07:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:07:47
Data point term sent to Coder	System	22 Sep 2020 20:39:00
User entered 'Calcium'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'Electrolyte Replacement for Vomiting'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered '1'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'tablet (TABLET)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'once daily (QD)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'Oral (ORAL)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered empty.	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered '14 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered '0'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered 'No (N)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User entered '16 Sep 2020'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:18:55
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:14:40
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' answered with 'mistake' (Site from DM).	Sharon Mathys (b) (4)	30 Oct 2020 15:33:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	30 Oct 2020 15:33:13
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of VOMITING in eDiary. Please note that this CM was given past Day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 04:15:18
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 20:38:53

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[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) (b) (4)	07 Oct 2020 16:14:44
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 16:14:44
Data point term sent to Coder	System	07 Oct 2020 16:10:36
User entered 'Influenza Vaccine'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Indication](#)

Audit	User	Time (GMT)
User entered 'Flu vaccination'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

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

Audit	User	Time (GMT)
User entered '5 Oct 2020'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:33:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:09:51

US3522269

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:33:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	22 Sep 2020 20:20:27

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'USA-US131-2020-MRNA-1273-P301000005'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Paul'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Kilgore'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'MI'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered 'US'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Oct 2020 12:50:53
User entered '2'	System	02 Oct 2020 12:28:01
User entered '1'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'USA-US131-2020-MRNA-1273-P301000005'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Paul'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Kilgore'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'MI'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered 'US'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Oct 2020 12:50:53
User entered '2'	System	02 Oct 2020 12:28:01
User entered '1'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:33:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
User entered '23/Sep/2020 07:53'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:33:08

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 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'USA-US131-2020-MRNA-1273-P301000005'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Paul'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Kilgore'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'MI'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered 'US'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Oct 2020 12:50:53
User entered '2'	System	02 Oct 2020 12:28:01
User entered '1'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:33:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
User entered '02/Oct/2020 12:28'	System	02 Oct 2020 12:28:01

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:33:08

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 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:50:13
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 12:28:01

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'USA-US131-2020-MRNA-1273-P301000005'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Yes (Y)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'No (N)'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Paul'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'Kilgore'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered 'MI'	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	23 Sep 2020 11:53:10
User entered (b) (6)	System	23 Sep 2020 11:52:16

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
Reviewed for Safety.	(b) (4), (b) (6)	02 Oct 2020 12:27:50
User entered 'US'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 26 Nov 2020 09:33:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Oct 2020 12:50:53
User entered '2'	System	02 Oct 2020 12:28:01
User entered '1'	System	23 Sep 2020 11:53:18

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:33:08

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 20:11:51
User entered '02/Oct/2020 12:50'	System	02 Oct 2020 12:50:53

US3522269

Folder: SAE USA-US131-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:33:08

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 20:11:51
User entered '1'	(b) (4), (b) (6)	02 Oct 2020 12:50:53