

US3662181 (Prod: Cincinnati CRS)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:09:02

All time stamps listed in this document are displayed in GMT

US3662181

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:02

[Participant ID](#)

US3662181

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

US3662181

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	True
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

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

Date of Informed Consent (<i>dd MMM yyyy</i>)	22 OCT 2020
Month and Year of Informed Consent (derived)	OCT 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

US3662181

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:02

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3662181

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:02

Were any significant conditions reported?

Yes ☒

No ☐

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

Condition	HYPERLIPIDEMIA, UNSPECIFIED
Start date (dd MMM yyyy)	15 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

Condition	LOW VON WILLEBRAND FACTOR
Start date (dd MMM yyyy)	15 JUL 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

Condition	UNSPECIFIED ACUTE RENAL FAILURE
Start date (dd MMM yyyy)	15 JUL 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

Condition	HYPERTENSION NEC
Start date (dd MMM yyyy)	15 JUL 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

Condition	UNSPECIFIED GLAUCOMA
Start date (dd MMM yyyy)	15 JUL 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

Condition	HYPERPARATHYROIDISM
Start date (dd MMM yyyy)	15 JUL 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

Condition	BIPOLAR AFFECTIVE DISORDER UNSPECIFIED
Start date (dd MMM yyyy)	15 JUL 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

Condition	GENERALIZED ANXIETY DISORDER
Start date (dd MMM yyyy)	15 JUL 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

Condition	MAJOR DEPRESSIVE DISORDER RECUR EPIS MILD
Start date (dd MMM yyyy)	15 JUL 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

Condition	SCHIZO-AFFECT SHIZO UNSPECIFIED CONDITION
Start date (dd MMM yyyy)	15 JUL 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	22 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:35 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:35
Height (<i>xxx.x</i>)	171.5 cm
Weight (<i>xxx.x</i>)	96.9 kg
BMI (<i>xxx.x</i>)	32.94546 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)	

US3662181

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

Occupational Risk

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

Specify

Location and Living Circumstances Risk (check all that apply)

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

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:02

What was the date of randomization? (dd MMM yyyy) 22 OCT 2020

What was the participant's randomization number? 117833

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 ☒

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:02

Height	ND - Not Done
Weight	ND - Not Done

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

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)	22 OCT 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:35
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

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)	22 OCT 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 13:59
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☐ Axillary ☐ Other ☒
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:02

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.

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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 OCT 2020
What was the treatment time? (00:00-23:59)	13:14 (24 HR)
Treatment Date and Time (derived)	22 OCT 2020 13:14
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

US3662181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:02

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

22 OCT 2020

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

11:55 (24 HR)

Collection date and time (derived)

22 OCT 2020 11:55

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:02

Collection date (<i>dd MMM yyyy</i>)			22 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:50	22 OCT 2020 11:50
Nasopharyngeal Swab 2	No		

US3662181

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 13:53

PC Open Date & Time

22 OCT 2020 13:34

PC Close Date & Time

22 OCT 2020 16:04

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	22 OCT 2020 23:06
PC Open Date & Time	22 OCT 2020 16:59
PC Close Date & Time	23 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

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

97.6 °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 23 OCT 2020 20:10

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

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

96.5 °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

24 OCT 2020 19:35

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 20:28

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 26 OCT 2020 12:00

PC Close Date & Time 27 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:02

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 27 OCT 2020 12:00

PC Close Date & Time 28 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:02

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 28 OCT 2020 12:00

PC Close Date & Time 29 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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 OCT 2020 13:41

PC Open Date & Time

22 OCT 2020 13:34

PC Close Date & Time

22 OCT 2020 16:04

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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 OCT 2020 23:07

PC Open Date & Time

22 OCT 2020 16:59

PC Close Date & Time

23 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

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 OCT 2020 20:10

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

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 ☐

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 - **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 OCT 2020 19:37

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

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 OCT 2020 20:29

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

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)**

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:02

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)**

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:02

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 13:42
PC Open Date & Time	22 OCT 2020 13:34
PC Close Date & Time	22 OCT 2020 16:04

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 23:07
PC Open Date & Time	22 OCT 2020 16:59
PC Close Date & Time	23 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

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 ☒

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

Yes ☐	
PC Time stamp	23 OCT 2020 20:11
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

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 ☒

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

Yes ☐	
PC Time stamp	24 OCT 2020 19:37
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

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 ☒

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

Yes ☐	
PC Time stamp	25 OCT 2020 20:30
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

CALLED AND TEXTED
PARTICIPANT- LEFT MESSAGE.
PHONE WENT STRAIGHT TO
VOICE MAIL

If Contact Not Made, please provide Comments

US3662181

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662181

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662181

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	19 NOV 2020
Time of assessment (00:00-23:59)	09:52 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 09:52
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	19 NOV 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 11:10
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED THERMOMETER
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3662181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:02

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 NOV 2020

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

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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)	19 NOV 2020
What was the treatment time? (00:00-23:59)	10:39 (24 HR)
Treatment Date and Time (derived)	19 NOV 2020 10:39
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

US3662181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:02

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 NOV 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

19 NOV 2020 10:15

US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:02

Collection date (<i>dd MMM yyyy</i>)			19 NOV 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:10	19 NOV 2020 10:10
Nasopharyngeal Swab 2	No		

US3662181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 NOV 2020 11:09

PC Open Date & Time

19 NOV 2020 10:59

PC Close Date & Time

19 NOV 2020 13:29

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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 98.3 °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	19 NOV 2020 22:26
PC Open Date & Time	19 NOV 2020 14:24
PC Close Date & Time	20 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

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

98.2 °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

20 NOV 2020 19:15

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 NOV 2020 19:18

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

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

98.3 °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

22 NOV 2020 20:09

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 NOV 2020 20:42

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:02

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 24 NOV 2020 12:00

PC Close Date & Time 25 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:02

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 25 NOV 2020 12:00

PC Close Date & Time 26 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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

19 NOV 2020 11:10

PC Open Date & Time

19 NOV 2020 10:59

PC Close Date & Time

19 NOV 2020 13:29

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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

19 NOV 2020 22:26

PC Open Date & Time

19 NOV 2020 14:24

PC Close Date & Time

20 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

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

20 NOV 2020 19:16

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

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

21 NOV 2020 19:19

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

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

22 NOV 2020 20:10

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

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

23 NOV 2020 20:43

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:02

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)**

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:02

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 11:10
PC Open Date & Time	19 NOV 2020 10:59
PC Close Date & Time	19 NOV 2020 13:29

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 22:27
PC Open Date & Time	19 NOV 2020 14:24
PC Close Date & Time	20 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

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 ☒

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

Yes ☐	
PC Time stamp	20 NOV 2020 19:17
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

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 ☒

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

Yes ☐	
PC Time stamp	21 NOV 2020 19:19
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

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 ☒

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

Yes ☐	
PC Time stamp	22 NOV 2020 20:10
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

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 ☒

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

Yes ☐	
PC Time stamp	23 NOV 2020 20:43
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:02

Yes ☐

PC Time stamp

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3662181

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

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13 JAN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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27 JAN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 FEB 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 MAR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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24 MAR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 MAR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 APR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 APR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 FEB 2022 00:01

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16 FEB 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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23 FEB 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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26 FEB 2022 00:01

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02 MAR 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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09 MAR 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

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16 MAR 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

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23 MAR 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

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20 APR 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

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27 APR 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

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06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

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13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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24 AUG 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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31 AUG 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

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21 SEP 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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24 SEP 2022 00:01

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28 SEP 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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 OCT 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

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12 OCT 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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19 OCT 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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26 OCT 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2022 23:59

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2022 23:59

US3662181

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:09:02

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☐

US3662181

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:09:02

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3662181

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:02

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

AEID	USA-US088-2020-MRNA-1273-P30 1000003
Adverse event	PSYCHOSIS, UNSPECIFIED
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)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	326 of 1652

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

HISTORY OF PRESENT ILLNESS:
61 YEAR OLD MALE WITH A
HISTORY OF BAD,
SCHIZOPHRENIA WHO
PRESENTED TO PES LOBBY
WITH CASE MANGER
YESTERDAY AFTER BEING AT
STORE AND TALKING TO THE
CASE MANAGER ABOUT
OBTAINING A FIREARM TO
SHOOT PEOPLE
PSYCHIATRIC HISTORY: HX
BAD, SCHIZOPHRENIA,
PARANOIA. PT LONG TIME
OUTPT FOLLOW UP WITH
CENTRAL CLINIC CM. PT HAS
APPROX 4 SUICIDE ATTEMPTS
IN HIS HISTORY, INCLUDING
(b) (6).
LAST ATTEMPT 2007. PT HAS
HX 2 ADMISSIONS, ONE AT BRV
IN FEB 2020 FOR SI AND ONE
HERE IN 2013. PT SAYS THAT
HE HAS A REMOTE HISTORY OF
VIOLENCE, LAST SPENDING
TIME IN JC IN LATE 90'S FOR
ASSAULT

HE HAS UNDERGONE
COMPREHENSIVE
PSYCHIATRIC EVALUATION
AND THERAPEUTIC
MANAGEMENT IN
ACCORDANCE WITH THE PES
GUIDELINES FOR PSYCHOSIS
NOS. BASED ON HIS CLINICAL
RESPONSE AND INFORMATION
OBTAINED DURING THIS
PERIOD OF OBSERVATION, IT
HAS BEEN DETERMINED THAT
HE WILL BE ADMITTED TO THE
HOSPITAL FOR ONGOING
MANAGEMENT

Serious Adverse Event Derived (CSA Programming Field Only)

1

v6.020 DTW (1102)

328 of 1652

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:02

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

Yes ☒

No ☐

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

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

Name of Medication	CAPLYTA
Prophylaxis	Yes ☐ No ☒
Indication	BIPOLAR DISORDER
Dose per administration	42
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 ☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

	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)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

Name of Medication	ESCITALOPRAM
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

	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)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

	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)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	BLOOD THINNER
Dose per administration	81
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 ☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

	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)		15 JUL 2018
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

	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)		15 JUL 2018
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

Name of Medication	GARLIC
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	1000
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

	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)		15 JUL 2015
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

	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)	15 JUL 2015	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

	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)		15 JUL 2014
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

Name of Medication	VITAMIN E
Prophylaxis	Yes ☒ No ☐
Indication	SUPPLEMENT
Dose per administration	268
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 ☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

	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)	15 JUL 2014	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

Name of Medication	SAPHRIS
Prophylaxis	Yes ☐ No ☒
Indication	BIPOLAR DISORDER
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

	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)		15 JUL 2013
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

Name of Medication	TIMOLOL MALEATE
Prophylaxis	Yes ☐ No ☒
Indication	GLAUCOMA
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	GTTS
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 ☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify		OU
Start date (dd MMM yyyy)		15 JUL 2010
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

Name of Medication	SODIUM BICARBONATE
Prophylaxis	Yes ☐ No ☒
Indication	CHRONIC RENAL DISEASE
Dose per administration	250
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

	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)		15 JUL 2015
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

Name of Medication	RISPERIDONE
Prophylaxis	Yes ☐ No ☒
Indication	BIPOLAR DISORDER
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 ☐ Intramuscular ☐

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

	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)		04 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3662181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:09:02

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3662181

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:09:02

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

US3662181

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:09:02

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 ☐

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

SAEID	USA-US088-2020-MRNA-1273-P301000003
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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	200 ALBERT SABIN WAY CINCINNATI, OH
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:02

SAEID	USA-US088-2020-MRNA-1273-P301000003
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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	200 ALBERT SABIN WAY CINCINNATI, OH
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	04/NOV/2020 15:08
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.	True

Audit

US3662181 (Prod: Cincinnati CRS)

US3662181

Form: Participant Creation

Generated On: 26 Nov 2020 11:09:02

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3662181'	RWS_ENDPOINT ENDPOINT (b) (4) 	22 Oct 2020 15:08:40

US3662181

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:52:12

US3662181

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	22 Oct 2020 15:08:41

US3662181

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:52:12

US3662181

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	27 Oct 2020 15:52:12

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	22 Oct 2020 15:08:42

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[Age](#)

Audit	User	Time (GMT)
User entered '61'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '61'	System	22 Oct 2020 16:48:04

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

White

Audit	User	Time (GMT)
User entered '1'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[Black](#)

Audit	User	Time (GMT)
User entered '1'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:09:02

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:09

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 Oct 2020'	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 16:48:04

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	22 Oct 2020 16:48:04

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '2020'	System	22 Oct 2020 16:48:04

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 4 (4)'	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 16:48:04

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 16:48:04

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 16:48:04

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 16:48:04

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 16:48:04

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	22 Oct 2020 15:08:41

US3662181

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:09:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 16:48:08

US3662181

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 16:48:08

US3662181

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:09:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:53:43

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:55:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:55:46
Data point term sent to Coder	System	27 Oct 2020 15:54:54
User entered 'HYPERLIPIDEMIA, UNSPECIFIED'	Brenda Miller (b) (4)	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Jul 2020'	System	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '2020'	System	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:54:20

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Blood and lymphatic system disorders congenital, HLT: Coagulation disorders congenital, PT: Von Willebrand's disease, LLT: Von Willebrand's factor deficiency - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:23:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:23:15
Data point term sent to Coder	System	24 Nov 2020 04:28:31
Query 'Per MM, please confirm if this condition meets the EC #8 'Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy'.	michelle saemann (b) (4) (b) (4)	24 Nov 2020 04:27:46
' answered with 'event term updated' (Site from DM).		
Coding entries removed.	michelle saemann (b) (4) (b) (4)	24 Nov 2020 04:27:38
User entered 'Low von Willebrand factor' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	24 Nov 2020 04:27:38
User opened query 'Per MM, please confirm if this condition meets the EC #8 'Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy'.	(b) (4), (b) (6)	20 Nov 2020 18:17:01
' (Site from DM).		
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Coagulopathies and bleeding diatheses (excl thrombocytopenic), HLT: Coagulopathies, PT: Coagulopathy, LLT: Defect coagulation (NOS) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:06:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:06:33
Data point term sent to Coder	System	27 Oct 2020 15:54:57
User entered 'COAGULATION DEFECT, UNSPECIFIED'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2015'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Jul 2015'	System	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '2015'	System	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:54:48

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure, unspecified - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:26:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:26:24
Data point term sent to Coder	System	27 Oct 2020 15:55:58
User entered 'UNSPECIFIED ACUTE RENAL FAILURE'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:14

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2015'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:14

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:14

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:14

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:14

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:14

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Jul 2015'	System	27 Oct 2020 15:55:14

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '2015'	System	27 Oct 2020 15:55:14

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:55:14

US3662181

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:55:14

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:56:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:56:35
Data point term sent to Coder	System	27 Oct 2020 15:55:59
User entered 'HYPERTENSION NEC'	Brenda Miller (b) (4)	27 Oct 2020 15:55:38
	(b) (4)	

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2014'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:38

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:38

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 15:56:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 15:56:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	27 Oct 2020 15:56:34
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 15:55:38
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 15:55:38

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:38

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:55:38

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Jul 2014'	System	27 Oct 2020 15:55:38

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '2014'	System	27 Oct 2020 15:55:38

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:55:38

US3662181

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:55:38

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Unspecified glaucoma - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:57:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:57:39
Data point term sent to Coder	System	27 Oct 2020 15:57:04
User entered 'UNSPECIFIED GLAUCOMA'	Brenda Miller (b) (4)	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2000'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Jul 2000'	System	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '2000'	System	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:56:59

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLT: Parathyroid gland disorders, HLT: Hyperparathyroid disorders, PT: Hyperparathyroidism, LLT: Hyperparathyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:59:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:59:40
Data point term sent to Coder	System	27 Oct 2020 15:58:06
User entered 'HYPERPARATHYROIDISM'	Brenda Miller (b) (4)	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 1980'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Jul 1980'	System	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '1980'	System	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:57:24

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar affective disorder, unspecified - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 21:35:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 21:35:34
Data point term sent to Coder	System	27 Oct 2020 15:58:13
User entered 'BIPOLAR AFFECTIVE DISORDER UNSPECIFIED'	Brenda Miller (b) (4)	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 1974'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Jul 1974'	System	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '1974'	System	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:57:46

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety disorders NEC, PT: Generalised anxiety disorder, LLT: Generalized anxiety disorder - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:59:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Oct 2020 15:59:40
Data point term sent to Coder	System	27 Oct 2020 15:58:15
User entered 'GENERALIZED ANXIETY DISORDER'	Brenda Miller (b) (4)	27 Oct 2020 15:58:09

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 1974'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:09

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:09

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:09

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:09

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:09

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Jul 1974'	System	27 Oct 2020 15:58:09

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '1974'	System	27 Oct 2020 15:58:09

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:58:09

US3662181

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:58:09

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Major depression, LLT: Major depressive disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:14:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:14:23
Data point term sent to Coder	System	27 Oct 2020 15:59:21
User entered 'MAJOR DEPRESSIVE DISORDER RECUR EPIS MILD'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 1974'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Jul 1974'	System	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '1974'	System	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:58:37

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Schizoaffective and schizophreniform disorders, PT: Schizoaffective disorder, LLT: Schizoaffective disorder - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 14:04:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 14:04:33
Data point term sent to Coder	System	27 Oct 2020 15:59:19
User entered 'SCHIZO-AFFECT SHIZO UNSPECIFIED CONDITION'	Brenda Miller (b) (4)	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 1974'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Jul 1974'	System	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '1974'	System	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:59:05

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '11:35'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:35'	System	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '171.5' cm	Brenda Miller (b) (4)	27 Oct 2020 16:00:16
DataPoint set to visible.	(b) (4) System	22 Oct 2020 16:48:08

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '96.9' kg	Brenda Miller (b) (4)	27 Oct 2020 16:00:16
DataPoint set to visible.	(b) (4) System	22 Oct 2020 16:48:08

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '32.94546'	System	27 Oct 2020 16:00:16
DataPoint set to visible.	System	22 Oct 2020 16:48:08

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	27 Oct 2020 16:00:16
DataPoint set to visible.	System	22 Oct 2020 16:48:08

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:09:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 16:00:16

US3662181

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:28

US3662181

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:00:28

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '1'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:09:02

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:01:24

US3662181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:02:05

US3662181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:02:05

US3662181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:02:05

US3662181

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	27 Oct 2020 16:02:05

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	22 Oct 2020 16:28:45

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:02

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '117833'	RWS_ENDPOINT ENDPOINT (b) (4) 	22 Oct 2020 16:28:45

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:02

[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) 	22 Oct 2020 16:28:45

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:02

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)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:02:34

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:02:34

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:02:34

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:02:34

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:02

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:02:34

US3662181

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:02:34
DataPoint set to visible.	(b) (4) System	22 Oct 2020 16:48:04

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:02

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:02

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:02

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:02

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '11:35'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:35'	System	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '16'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '113'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:02

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:09:02

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '13:59'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 Oct 2020 13:59'	System	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '67'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '16'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '86'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 16:04:30

US3662181

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:02

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:36

US3662181

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:04:36

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '13:14'	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 Oct 2020 13:14'	System	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4) (b) (4)	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	22 Oct 2020 17:17:48

US3662181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:02

US3662181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:02

US3662181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:55'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:02

US3662181

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:55'	System	27 Oct 2020 16:08:02

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Oct 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:19

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:02

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:19

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:19

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:50'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:19

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:50'	System	27 Oct 2020 16:08:19

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:02

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4)	27 Oct 2020 16:08:19

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:19

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:19

US3662181

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:08:19

US3662181

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:24

US3662181

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:08:24

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:53:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7c59e80e-5671-4c34-be70-64756cce9aaf'	System	22 Oct 2020 17:53:28
User entered 'Yes (Y)'	System	22 Oct 2020 17:53:28

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:53:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7c59e80e-5671-4c34-be70-64756cce9aaf'	System	22 Oct 2020 17:53:28
User entered '97.8'	System	22 Oct 2020 17:53:28

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:53:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7c59e80e-5671-4c34-be70-64756cce9aaf'	System	22 Oct 2020 17:53:28
User entered 'No (N)'	System	22 Oct 2020 17:53:28

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:53:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7c59e80e-5671-4c34-be70-64756cce9aaf'	System	22 Oct 2020 17:53:28
User entered '22 Oct 2020 13:53'	System	22 Oct 2020 17:53:28

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 13:34'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 16:04'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:05:42', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6222c04d-c40a-48dd-896a-0cadaba472ed'	System	23 Oct 2020 03:06:13
User entered 'Yes (Y)'	System	23 Oct 2020 03:06:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:05:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6222c04d-c40a-48dd-896a-0cadaba472ed'	System	23 Oct 2020 03:06:13
User entered '97.6'	System	23 Oct 2020 03:06:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:05:57', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6222c04d-c40a-48dd-896a-0cadaba472ed'	System	23 Oct 2020 03:06:13
User entered 'No (N)'	System	23 Oct 2020 03:06:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:06:06', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6222c04d-c40a-48dd-896a-0cadaba472ed'	System	23 Oct 2020 03:06:13
User entered '22 Oct 2020 23:06'	System	23 Oct 2020 03:06:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 16:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 2'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:09:50', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '41d2bc2d-1116-423a-95c8-db0e63a56d4d'	System	24 Oct 2020 00:10:13
User entered 'Yes (Y)'	System	24 Oct 2020 00:10:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:09:58', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '41d2bc2d-1116-423a-95c8-db0e63a56d4d'	System	24 Oct 2020 00:10:13
User entered '97.6'	System	24 Oct 2020 00:10:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:03', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '41d2bc2d-1116-423a-95c8-db0e63a56d4d'	System	24 Oct 2020 00:10:13
User entered 'No (N)'	System	24 Oct 2020 00:10:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:10', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '41d2bc2d-1116-423a-95c8-db0e63a56d4d'	System	24 Oct 2020 00:10:13
User entered '23 Oct 2020 20:10'	System	24 Oct 2020 00:10:13

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 3'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:34:37', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '574b5613-8995-4321-b5b0-ff7118f6406b'	System	24 Oct 2020 23:35:08
User entered 'Yes (Y)'	System	24 Oct 2020 23:35:08

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:34:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '574b5613-8995-4321-b5b0-ff7118f6406b'	System	24 Oct 2020 23:35:08
User entered '96.5'	System	24 Oct 2020 23:35:08

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:34:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '574b5613-8995-4321-b5b0-ff7118f6406b'	System	24 Oct 2020 23:35:08
User entered 'No (N)'	System	24 Oct 2020 23:35:08

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:35:01', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '574b5613-8995-4321-b5b0-ff7118f6406b'	System	24 Oct 2020 23:35:08
User entered '24 Oct 2020 19:35'	System	24 Oct 2020 23:35:08

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 4'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:27:49', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '70fa55f9-9eb7-47e9-935a-eef15847246b'	System	26 Oct 2020 00:28:11
User entered 'Yes (Y)'	System	26 Oct 2020 00:28:11

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:27:56', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '70fa55f9-9eb7-47e9-935a-eef15847246b'	System	26 Oct 2020 00:28:11
User entered '96.9'	System	26 Oct 2020 00:28:11

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:28:02', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '70fa55f9-9eb7-47e9-935a-eef15847246b'	System	26 Oct 2020 00:28:11
User entered 'No (N)'	System	26 Oct 2020 00:28:11

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:28:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '70fa55f9-9eb7-47e9-935a-eef15847246b'	System	26 Oct 2020 00:28:11
User entered '25 Oct 2020 20:28'	System	26 Oct 2020 00:28:11

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 5'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 6'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 7'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:40:46', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7f8a520-b9b0-4c22-83fe-a2aabe41909b'	System	22 Oct 2020 17:41:54
User entered 'None (1)'	System	22 Oct 2020 17:41:54

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:40:51', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7f8a520-b9b0-4c22-83fe-a2aabe41909b'	System	22 Oct 2020 17:41:54
User entered 'No (N)'	System	22 Oct 2020 17:41:54

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:40:59', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7f8a520-b9b0-4c22-83fe-a2aabe41909b'	System	22 Oct 2020 17:41:54
User entered 'No (N)'	System	22 Oct 2020 17:41:54

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:41:33', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7f8a520-b9b0-4c22-83fe-a2aabe41909b'	System	22 Oct 2020 17:41:54
User entered 'None (1)'	System	22 Oct 2020 17:41:54

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:41:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a7f8a520-b9b0-4c22-83fe-a2aabe41909b'	System	22 Oct 2020 17:41:54
User entered '22 Oct 2020 13:41'	System	22 Oct 2020 17:41:54

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 13:34'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 16:04'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:06:17', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'bf5d13c2-3955-471a-9838-e77220522a34'	System	23 Oct 2020 03:07:10
User entered 'None (1)'	System	23 Oct 2020 03:07:10

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:06:27', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'bf5d13c2-3955-471a-9838-e77220522a34'	System	23 Oct 2020 03:07:10
User entered 'No (N)'	System	23 Oct 2020 03:07:10

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:06:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'bf5d13c2-3955-471a-9838-e77220522a34'	System	23 Oct 2020 03:07:10
User entered 'No (N)'	System	23 Oct 2020 03:07:10

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:04', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'bf5d13c2-3955-471a-9838-e77220522a34'	System	23 Oct 2020 03:07:10
User entered 'None (1)'	System	23 Oct 2020 03:07:10

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:08', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'bf5d13c2-3955-471a-9838-e77220522a34'	System	23 Oct 2020 03:07:10
User entered '22 Oct 2020 23:07'	System	23 Oct 2020 03:07:10

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 16:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 2'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '36f83a10-8057-4be4-bad9-242f31458dc0'	System	24 Oct 2020 00:10:40
User entered 'None (1)'	System	24 Oct 2020 00:10:40

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:22', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '36f83a10-8057-4be4-bad9-242f31458dc0'	System	24 Oct 2020 00:10:40
User entered 'No (N)'	System	24 Oct 2020 00:10:40

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:30', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '36f83a10-8057-4be4-bad9-242f31458dc0'	System	24 Oct 2020 00:10:40
User entered 'No (N)'	System	24 Oct 2020 00:10:40

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:34', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '36f83a10-8057-4be4-bad9-242f31458dc0'	System	24 Oct 2020 00:10:40
User entered 'None (1)'	System	24 Oct 2020 00:10:40

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:39', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '36f83a10-8057-4be4-bad9-242f31458dc0'	System	24 Oct 2020 00:10:40
User entered '23 Oct 2020 20:10'	System	24 Oct 2020 00:10:40

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 3'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:35:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered 'None (1)'	System	24 Oct 2020 23:37:06

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:35:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered 'Yes (Y)'	System	24 Oct 2020 23:37:06

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:36:15', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0' User entered '3'	System	24 Oct 2020 23:37:06

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:36:33', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered 'No (N)'	System	24 Oct 2020 23:37:06

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:36:56', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered 'None (1)'	System	24 Oct 2020 23:37:06

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:02', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6e41087a-e9e5-45d6-a325-8fc6dae95ed0'	System	24 Oct 2020 23:37:06
User entered '24 Oct 2020 19:37'	System	24 Oct 2020 23:37:06

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 4'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:28:18', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '44b66b50-64a9-43cf-b5b3-b37c54549b28'	System	26 Oct 2020 00:29:23
User entered 'None (1)'	System	26 Oct 2020 00:29:23

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:28:24', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '44b66b50-64a9-43cf-b5b3-b37c54549b28'	System	26 Oct 2020 00:29:23
User entered 'No (N)'	System	26 Oct 2020 00:29:23

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:28:45', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '44b66b50-64a9-43cf-b5b3-b37c54549b28'	System	26 Oct 2020 00:29:23
User entered 'No (N)'	System	26 Oct 2020 00:29:23

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:17', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '44b66b50-64a9-43cf-b5b3-b37c54549b28'	System	26 Oct 2020 00:29:23
User entered 'None (1)'	System	26 Oct 2020 00:29:23

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '44b66b50-64a9-43cf-b5b3-b37c54549b28'	System	26 Oct 2020 00:29:23
User entered '25 Oct 2020 20:29'	System	26 Oct 2020 00:29:23

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 5'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 6'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 7'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:00', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:13', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:20', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'None (0)'	System	22 Oct 2020 17:42:34

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered 'No (N)'	System	22 Oct 2020 17:42:34

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T13:42:32', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ae697bf1-6f26-402c-b867-0ff7aac242a5'	System	22 Oct 2020 17:42:34
User entered '22 Oct 2020 13:42'	System	22 Oct 2020 17:42:34

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 13:34'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 16:04'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:15', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:38', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'None (0)'	System	23 Oct 2020 03:07:51

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:42', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered 'No (N)'	System	23 Oct 2020 03:07:51

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-22T23:07:47', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'db2067dd-2bf0-492d-9075-24f0bc7cdb11'	System	23 Oct 2020 03:07:51
User entered '22 Oct 2020 23:07'	System	23 Oct 2020 03:07:51

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 16:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 2'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:44', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:50', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:55', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:10:57', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:11:00', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'None (0)'	System	24 Oct 2020 00:11:14

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:11:08', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered 'No (N)'	System	24 Oct 2020 00:11:14

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-23T20:11:11', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '332865df-cd95-4571-a82d-6bbde17181bb'	System	24 Oct 2020 00:11:14
User entered '23 Oct 2020 20:11'	System	24 Oct 2020 00:11:14

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 3'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:11', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:14', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:17', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:20', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:22', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'None (0)'	System	24 Oct 2020 23:37:39

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:30', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered 'No (N)'	System	24 Oct 2020 23:37:39

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-24T19:37:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '5874951f-3db5-4da3-8fed-27898e4a143b'	System	24 Oct 2020 23:37:39
User entered '24 Oct 2020 19:37'	System	24 Oct 2020 23:37:39

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 4'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:27', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:39', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:41', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:44', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'None (0)'	System	26 Oct 2020 00:30:02

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:29:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered 'No (N)'	System	26 Oct 2020 00:30:02

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-10-25T20:30:01', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'd06a6913-d87f-476e-a5ce-bf06e8d55410'	System	26 Oct 2020 00:30:02
User entered '25 Oct 2020 20:30'	System	26 Oct 2020 00:30:02

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 5'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 6'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	22 Oct 2020 17:17:48
User entered 'Day 7'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 17:17:48

US3662181

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 17:17:48

US3662181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 14:27:24
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 14:26:29
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:26:29

US3662181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '29 Oct 2020' reason for change: Data Entry Error	Brenda Miller (b) (4)	05 Nov 2020 14:27:24
User entered empty.	Brenda Miller (b) (4)	05 Nov 2020 14:26:29

US3662181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:26:29

US3662181

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'CALLED AND TEXTED PARTICIPANT- LEFT MESSAGE. PHONE WENT STRAIGHT TO VOICE MAIL'	Brenda Miller (b) (4)	05 Nov 2020 14:26:29

US3662181

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:09:13

US3662181

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Nov 2020 17:09:13

US3662181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:09:30

US3662181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '05 Nov 2020'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:09:30

US3662181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:09:30

US3662181

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:09:30

US3662181

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:09:37

US3662181

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Nov 2020 17:09:37

US3662181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	13 Nov 2020 15:32:04

US3662181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Brenda Miller (b) (4) (b) (4)	13 Nov 2020 15:32:04

US3662181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4) (b) (4)	13 Nov 2020 15:32:04

US3662181

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:09:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	13 Nov 2020 15:32:04

US3662181

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	13 Nov 2020 15:32:10

US3662181

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 15:32:10

US3662181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:26:37

US3662181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '19 Nov 2020'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:26:37

US3662181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:26:37

US3662181

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:09:02

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	19 Nov 2020 19:26:37

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '09:52'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 09:52'	System	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '16'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '119'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:09:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '11:10'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 11:10'	System	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '63'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '16'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:09:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 19:28:34

US3662181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:02

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:55

US3662181

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:09:02

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:28:55

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	MaKayla Bishop (b) (4) (b) (4)	19 Nov 2020 15:42:50

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	MaKayla Bishop (b) (4) (b) (4)	19 Nov 2020 15:42:50

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	MaKayla Bishop (b) (4) (b) (4)	19 Nov 2020 15:42:50

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	19 Nov 2020 15:42:50

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	MaKayla Bishop (b) (4) (b) (4)	19 Nov 2020 15:42:50

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '10:39'	MaKayla Bishop (b) (4) (b) (4)	19 Nov 2020 15:42:50

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 10:39'	System	19 Nov 2020 15:42:50

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	MaKayla Bishop (b) (4) (b) (4)	19 Nov 2020 15:42:50

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	19 Nov 2020 15:42:50

US3662181

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	19 Nov 2020 15:42:50

US3662181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:28

US3662181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:28

US3662181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:15'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:28

US3662181

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 10:15'	System	19 Nov 2020 19:29:28

US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:09:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:47

US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:02

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4)	19 Nov 2020 19:29:47

US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:47

US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:10'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:47

US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 10:10'	System	19 Nov 2020 19:29:47

US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:02

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4)	19 Nov 2020 19:29:47

US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:47

US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:47

US3662181

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 19:29:47

US3662181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	19 Nov 2020 19:29:54

US3662181

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:09:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 19:29:54

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:09:44', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b36b1f88-5370-4ef8-a476-1f201d68203d'	System	19 Nov 2020 16:10:03
User entered 'Yes (Y)'	System	19 Nov 2020 16:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:09:51', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b36b1f88-5370-4ef8-a476-1f201d68203d'	System	19 Nov 2020 16:10:03
User entered '97.9'	System	19 Nov 2020 16:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:09:54', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b36b1f88-5370-4ef8-a476-1f201d68203d'	System	19 Nov 2020 16:10:03
User entered 'No (N)'	System	19 Nov 2020 16:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:09:57', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'b36b1f88-5370-4ef8-a476-1f201d68203d'	System	19 Nov 2020 16:10:03
User entered '19 Nov 2020 11:09'	System	19 Nov 2020 16:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 10:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 13:29'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:25:47', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e2a9d11d-45ad-4453-9d94-cd8639fa596a'	System	20 Nov 2020 03:26:08
User entered 'Yes (Y)'	System	20 Nov 2020 03:26:08

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:25:56', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e2a9d11d-45ad-4453-9d94-cd8639fa596a'	System	20 Nov 2020 03:26:08
User entered '98.3'	System	20 Nov 2020 03:26:08

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:00', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e2a9d11d-45ad-4453-9d94-cd8639fa596a'	System	20 Nov 2020 03:26:08
User entered 'No (N)'	System	20 Nov 2020 03:26:08

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:04', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'e2a9d11d-45ad-4453-9d94-cd8639fa596a'	System	20 Nov 2020 03:26:08
User entered '19 Nov 2020 22:26'	System	20 Nov 2020 03:26:08

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 14:24'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 2'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:15:42', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a88b298c-1c5b-4d83-b29a-b5fda73cb877'	System	21 Nov 2020 00:18:43
User entered 'Yes (Y)'	System	21 Nov 2020 00:18:43

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:15:47', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a88b298c-1c5b-4d83-b29a-b5fda73cb877'	System	21 Nov 2020 00:18:43
User entered '98.2'	System	21 Nov 2020 00:18:43

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:15:51', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a88b298c-1c5b-4d83-b29a-b5fda73cb877'	System	21 Nov 2020 00:18:43
User entered 'No (N)'	System	21 Nov 2020 00:18:43

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:15:55', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a88b298c-1c5b-4d83-b29a-b5fda73cb877'	System	21 Nov 2020 00:18:43
User entered '20 Nov 2020 19:15'	System	21 Nov 2020 00:18:43

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 3'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:23', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '4b78e513-92cc-4c90-bcdc-fe8500bbccc9'	System	22 Nov 2020 00:18:38
User entered 'Yes (Y)'	System	22 Nov 2020 00:18:38

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:32', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '4b78e513-92cc-4c90-bcdc-fe8500bbccc9'	System	22 Nov 2020 00:18:38
User entered '97.3'	System	22 Nov 2020 00:18:38

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '4b78e513-92cc-4c90-bcdc-fe8500bbccc9'	System	22 Nov 2020 00:18:38
User entered 'No (N)'	System	22 Nov 2020 00:18:38

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:38', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '4b78e513-92cc-4c90-bcdc-fe8500bbccc9'	System	22 Nov 2020 00:18:38
User entered '21 Nov 2020 19:18'	System	22 Nov 2020 00:18:38

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 4'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:08:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '69976726-2284-4dba-b1f9-7217b6a68c76'	System	23 Nov 2020 01:09:18
User entered 'Yes (Y)'	System	23 Nov 2020 01:09:18

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:07', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '69976726-2284-4dba-b1f9-7217b6a68c76'	System	23 Nov 2020 01:09:18
User entered '98.3'	System	23 Nov 2020 01:09:18

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:12', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '69976726-2284-4dba-b1f9-7217b6a68c76'	System	23 Nov 2020 01:09:18
User entered 'No (N)'	System	23 Nov 2020 01:09:18

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:15', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '69976726-2284-4dba-b1f9-7217b6a68c76'	System	23 Nov 2020 01:09:18
User entered '22 Nov 2020 20:09'	System	23 Nov 2020 01:09:18

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 5'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6f71855d-5e5a-4e34-9102-0f5e2848edf5'	System	24 Nov 2020 01:42:41
User entered 'Yes (Y)'	System	24 Nov 2020 01:42:41

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:33', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6f71855d-5e5a-4e34-9102-0f5e2848edf5'	System	24 Nov 2020 01:42:41
User entered '97.9'	System	24 Nov 2020 01:42:41

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:37', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6f71855d-5e5a-4e34-9102-0f5e2848edf5'	System	24 Nov 2020 01:42:41
User entered 'No (N)'	System	24 Nov 2020 01:42:41

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:39', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '6f71855d-5e5a-4e34-9102-0f5e2848edf5'	System	24 Nov 2020 01:42:41
User entered '23 Nov 2020 20:42'	System	24 Nov 2020 01:42:41

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 6'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 7'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:03', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7fe1ccdc-a183-4a28-9961-e2b24c0b593b'	System	19 Nov 2020 16:10:32
User entered 'None (1)'	System	19 Nov 2020 16:10:32

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:06', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7fe1ccdc-a183-4a28-9961-e2b24c0b593b'	System	19 Nov 2020 16:10:32
User entered 'No (N)'	System	19 Nov 2020 16:10:32

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:12', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7fe1ccdc-a183-4a28-9961-e2b24c0b593b'	System	19 Nov 2020 16:10:32
User entered 'No (N)'	System	19 Nov 2020 16:10:32

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7fe1ccdc-a183-4a28-9961-e2b24c0b593b'	System	19 Nov 2020 16:10:32
User entered 'None (1)'	System	19 Nov 2020 16:10:32

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '7fe1ccdc-a183-4a28-9961-e2b24c0b593b'	System	19 Nov 2020 16:10:32
User entered '19 Nov 2020 11:10'	System	19 Nov 2020 16:10:32

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 10:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 13:29'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:14', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '08f2dd2d-5d24-4a0f-85e5-8f84629f689d'	System	20 Nov 2020 03:26:46
User entered 'None (1)'	System	20 Nov 2020 03:26:46

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:17', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '08f2dd2d-5d24-4a0f-85e5-8f84629f689d'	System	20 Nov 2020 03:26:46
User entered 'No (N)'	System	20 Nov 2020 03:26:46

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '08f2dd2d-5d24-4a0f-85e5-8f84629f689d'	System	20 Nov 2020 03:26:46
User entered 'No (N)'	System	20 Nov 2020 03:26:46

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:37', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '08f2dd2d-5d24-4a0f-85e5-8f84629f689d'	System	20 Nov 2020 03:26:46
User entered 'None (1)'	System	20 Nov 2020 03:26:46

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:41', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '08f2dd2d-5d24-4a0f-85e5-8f84629f689d'	System	20 Nov 2020 03:26:46
User entered '19 Nov 2020 22:26'	System	20 Nov 2020 03:26:46

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 14:24'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 2'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:15:59', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '253bf999-243e-4413-8aed-f250eab8fa4f'	System	21 Nov 2020 00:18:44
User entered 'None (1)'	System	21 Nov 2020 00:18:44

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:02', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '253bf999-243e-4413-8aed-f250eab8fa4f'	System	21 Nov 2020 00:18:44
User entered 'No (N)'	System	21 Nov 2020 00:18:44

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '253bf999-243e-4413-8aed-f250eab8fa4f'	System	21 Nov 2020 00:18:44
User entered 'No (N)'	System	21 Nov 2020 00:18:44

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:23', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '253bf999-243e-4413-8aed-f250eab8fa4f'	System	21 Nov 2020 00:18:44
User entered 'None (1)'	System	21 Nov 2020 00:18:44

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '253bf999-243e-4413-8aed-f250eab8fa4f'	System	21 Nov 2020 00:18:44
User entered '20 Nov 2020 19:16'	System	21 Nov 2020 00:18:44

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 3'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:43', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '172aad5d-a0da-41ba-ae15-19d2389272a9'	System	22 Nov 2020 00:19:11
User entered 'None (1)'	System	22 Nov 2020 00:19:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:46', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '172aad5d-a0da-41ba-ae15-19d2389272a9'	System	22 Nov 2020 00:19:11
User entered 'No (N)'	System	22 Nov 2020 00:19:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:18:49', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '172aad5d-a0da-41ba-ae15-19d2389272a9'	System	22 Nov 2020 00:19:11
User entered 'No (N)'	System	22 Nov 2020 00:19:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:06', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '172aad5d-a0da-41ba-ae15-19d2389272a9'	System	22 Nov 2020 00:19:11
User entered 'None (1)'	System	22 Nov 2020 00:19:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '172aad5d-a0da-41ba-ae15-19d2389272a9'	System	22 Nov 2020 00:19:11
User entered '21 Nov 2020 19:19'	System	22 Nov 2020 00:19:11

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 4'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ce96142a-2acd-466c-90af-091f2f6c50b9'	System	23 Nov 2020 01:10:03
User entered 'None (1)'	System	23 Nov 2020 01:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:29', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ce96142a-2acd-466c-90af-091f2f6c50b9'	System	23 Nov 2020 01:10:03
User entered 'No (N)'	System	23 Nov 2020 01:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:33', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ce96142a-2acd-466c-90af-091f2f6c50b9'	System	23 Nov 2020 01:10:03
User entered 'No (N)'	System	23 Nov 2020 01:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:09:56', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ce96142a-2acd-466c-90af-091f2f6c50b9'	System	23 Nov 2020 01:10:03
User entered 'None (1)'	System	23 Nov 2020 01:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:00', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'ce96142a-2acd-466c-90af-091f2f6c50b9'	System	23 Nov 2020 01:10:03
User entered '22 Nov 2020 20:10'	System	23 Nov 2020 01:10:03

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 5'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

[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 (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '073d5e0c-e5ab-4f05-93e9-157b35319ceb'	System	24 Nov 2020 01:43:07
User entered 'None (1)'	System	24 Nov 2020 01:43:07

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '073d5e0c-e5ab-4f05-93e9-157b35319ceb'	System	24 Nov 2020 01:43:07
User entered 'No (N)'	System	24 Nov 2020 01:43:07

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:42:59', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '073d5e0c-e5ab-4f05-93e9-157b35319ceb'	System	24 Nov 2020 01:43:07
User entered 'No (N)'	System	24 Nov 2020 01:43:07

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:03', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '073d5e0c-e5ab-4f05-93e9-157b35319ceb'	System	24 Nov 2020 01:43:07
User entered 'None (1)'	System	24 Nov 2020 01:43:07

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '073d5e0c-e5ab-4f05-93e9-157b35319ceb'	System	24 Nov 2020 01:43:07
User entered '23 Nov 2020 20:43'	System	24 Nov 2020 01:43:07

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 6'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 7'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:31', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:35', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:38', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:41', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:44', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:46', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'None (0)'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:53', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered 'No (N)'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T11:10:57', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '25a5acac-4d23-4e7e-bdb3-8db1275af858'	System	19 Nov 2020 16:11:00
User entered '19 Nov 2020 11:10'	System	19 Nov 2020 16:11:00

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 10:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 13:29'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:55', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:26:59', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:27:02', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:27:05', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'None (0)'	System	20 Nov 2020 03:27:16

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:27:09', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered 'No (N)'	System	20 Nov 2020 03:27:16

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-19T22:27:12', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '02b72040-f40c-422c-9190-d61a5e4ac29a'	System	20 Nov 2020 03:27:16
User entered '19 Nov 2020 22:27'	System	20 Nov 2020 03:27:16

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 14:24'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 2'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:32', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:36', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:40', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:43', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:45', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'None (0)'	System	21 Nov 2020 00:18:45

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:16:52', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered 'No (N)'	System	21 Nov 2020 00:18:45

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-20T19:17:01', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '58eccf19-1c39-4faa-ac69-49381e853011'	System	21 Nov 2020 00:18:45
User entered '20 Nov 2020 19:17'	System	21 Nov 2020 00:18:45

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 3'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:14', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f'	System	22 Nov 2020 00:19:50
User entered 'None (0)'	System	22 Nov 2020 00:19:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:26', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f'	System	22 Nov 2020 00:19:50
User entered 'None (0)'	System	22 Nov 2020 00:19:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:33', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f'	System	22 Nov 2020 00:19:50
User entered 'None (0)'	System	22 Nov 2020 00:19:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:36', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f'	System	22 Nov 2020 00:19:50
User entered 'None (0)'	System	22 Nov 2020 00:19:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:40', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f'	System	22 Nov 2020 00:19:50
User entered 'None (0)'	System	22 Nov 2020 00:19:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:43', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f'	System	22 Nov 2020 00:19:50
User entered 'None (0)'	System	22 Nov 2020 00:19:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:46', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f'	System	22 Nov 2020 00:19:50
User entered 'No (N)'	System	22 Nov 2020 00:19:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-21T19:19:48', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '327fa11e-8017-40c5-a28a-090f505f951f'	System	22 Nov 2020 00:19:50
User entered '21 Nov 2020 19:19'	System	22 Nov 2020 00:19:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 4'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:08', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:11', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:29', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'None (0)'	System	23 Nov 2020 01:10:42

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:36', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered 'No (N)'	System	23 Nov 2020 01:10:42

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-22T20:10:39', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: 'a07e84f7-630e-48a4-bea9-723a380ddbaf'	System	23 Nov 2020 01:10:42
User entered '22 Nov 2020 20:10'	System	23 Nov 2020 01:10:42

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 5'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:10', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:14', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:16', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:19', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:21', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:25', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'None (0)'	System	24 Nov 2020 01:43:30

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

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 (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:28', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered 'No (N)'	System	24 Nov 2020 01:43:30

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d1dbddc93e6bc7ef)', Time: '2020-11-23T20:43:30', User OID: 'PatientReportedOutcome (US3662181)', ODM File OID: '88c88396-1227-4c6b-be45-12315172899b'	System	24 Nov 2020 01:43:30
User entered '23 Nov 2020 20:43'	System	24 Nov 2020 01:43:30

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 6'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 15:42:50
User entered 'Day 7'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 15:42:50

US3662181

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:09:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 15:42:50

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '10 Dec 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '14 Dec 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '17 Dec 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '21 Dec 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '24 Dec 2022 00:01'	System	20 Nov 2020 13:29:36

US3662181

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:09:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:29:36
Amendment Manager: User entered '28 Dec 2022 23:59'	System	20 Nov 2020 13:29:36

US3662181

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:09:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:24
User entered 'Yes (Y)'	michelle saemann (b) (4)	03 Nov 2020 14:48:57
	(b) (4)	

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:39
User entered 'USA-US088-2020-mRNA-1273-P301000003'	System	04 Nov 2020 15:07:33
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 15:07:33

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User coded data point as SOC: Psychiatric disorders, HLGT: Schizophrenia and other psychotic disorders, HLT: Psychotic disorder NEC, PT: Psychotic disorder, LLT: Unspecified psychosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:05:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:05:23
Data point term sent to Coder	System	03 Nov 2020 14:58:16
User entered 'Psychosis, unspecified'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Yes (Y)'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'No (N)'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'No (N)'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '26 Oct 2020'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered empty.	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'No (N)'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '30 Oct 2020'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered empty.	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Grade 3/Severe (Grade 3/Severe)'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Yes (Y)'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '1'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: The narrative stated the subject was with the case manager yesterday and talked about shooting people. Please clarify the start date of the event. Did symptoms start the day of hospitalization 26 Oct 2020 or yesterday 25 Oct 2020?' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:22:30
Query 'PV Query: The narrative stated the subject was with the case manager yesterday and talked about shooting people. Please clarify the start date of the event. Did symptoms start the day of hospitalization 26 Oct 2020 or yesterday 25 Oct 2020?' answered with 'Date entered correct per source document' (Site from Safety).	Brenda Miller (b) (4)	23 Nov 2020 13:30:34
User opened query 'PV Query: The narrative stated the subject was with the case manager yesterday and talked about shooting people. Please clarify the start date of the event. Did symptoms start the day of hospitalization 26 Oct 2020 or yesterday 25 Oct 2020?' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:03:01
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '26 Oct 2020'	michelle saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '30 Oct 2020'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'No (N)'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered empty.	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:57:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Nov 2020 14:57:40
User entered 'None (NONE)' reason for change: Data Entry Error	michelle saemann (b) (4)	03 Nov 2020 14:57:40
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Nov 2020 14:57:16
User entered empty.	michelle saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '1'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered '0'	Michelle Saemann (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered empty.	michelle saemann (b) (4)	03 Nov 2020 14:57:16
	(b) (4)	

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Narrative](#)

Audit	User	Time (GMT)
Query 'Please replace Yesterday with actual date: PRESENTED TO PES LOBBY WITH CASE MANAGER YESTERDAY - 26 Oct 2020' canceled (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:15:00
User opened query 'Please replace Yesterday with actual date: PRESENTED TO PES LOBBY WITH CASE MANAGER YESTERDAY - 26 Oct 2020' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:11:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:03:24
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:03:11
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:06:06
User entered 'History of Present Illness: 61 year old male with a History of BAD, schizophrenia who presented to PES lobby with case manger yesterday after being at store and talking to the case manager about obtaining a firearm to shoot people Psychiatric History: HX BAD, Schizophrenia, paranoia. Pt long time outpt follow up with central clinic CM. Pt has approx 4 suicide attempts in his history, including (b) (6). Last attempt 2007. Pt has hx 2 admissions, one at BRV in Feb 2020 for SI and one here in 2013. Pt says that he has a remote history of violence, last spending time in JC in late 90's for assault He has undergone comprehensive psychiatric evaluation and therapeutic management in accordance with the PES guidelines for psychosis nos. Based on his clinical response and information obtained during this period of observation, it has been determined that he will be admitted to the hospital for ongoing management'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 14:57:16

US3662181

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:09:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Nov 2020 14:57:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:09:02

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:08:57

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: BUTYROPHENONE DERIVATIVES, PRODUCT: LUMATEPERONE TOSYLATE, PRODUCTSYNONYM: CAPLYTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:10:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:10:49
Data point term sent to Coder	System	27 Oct 2020 16:09:44
User entered 'CAPLYTA'	Brenda Miller (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'BIPOLAR DISORDER'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '42'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:09:38

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:11:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:11:35
Data point term sent to Coder	System	27 Oct 2020 16:10:45
User entered 'ESCITALOPRAM'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:46
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:52
User entered 'DEPRESSION'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:53
User entered '10'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:58
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:59
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:01
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:03
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:07
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:09
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:10
User entered '15 Sep 2020'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:12
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:14
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:15
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:10:18
	(b) (4)	

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:19:19
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:10:18

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:12:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:12:38
Data point term sent to Coder	System	27 Oct 2020 16:11:45
User entered 'HYDROXYZINE'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:20
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:22
User entered 'ANXIETY'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:17:27
User entered '50'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:03
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:05
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:07
User entered 'as needed (PRN)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:12
User entered empty.	Brenda Miller (b) (4)	27 Oct 2020 16:10:49
	(b) (4)	

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:13
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:14
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:18
User entered '15 Sep 2020'	Brenda Miller (b) (4)	27 Oct 2020 16:10:49
	(b) (4)	

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:20
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:36
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:38
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:18:40
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 16:10:49

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:12:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:12:38
Data point term sent to Coder	System	27 Oct 2020 16:11:46
User entered 'ASPIRIN'	Brenda Miller (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'BLOOD THINNER'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2018'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:11:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:13:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:13:38
Data point term sent to Coder	System	27 Oct 2020 16:12:47
User entered 'ATORVASTATIN'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'HYPERLIPIDEMIA'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2018'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:11:51

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:13:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:13:39
Data point term sent to Coder	System	27 Oct 2020 16:12:46
User entered 'GARLIC'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	01 Nov 2020 15:09:06
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'SUPPLEMENT'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2015'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:12:20

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:15:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:15:43
Data point term sent to Coder	System	27 Oct 2020 16:14:51
User entered 'VITAMIN B COMPLEX'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	01 Nov 2020 15:09:24
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'SUPPLEMENT'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2015'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:14:29

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:16:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:16:36
Data point term sent to Coder	System	27 Oct 2020 16:15:55
User entered 'AMLODIPINE BESYLATE'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'HYPERTENSION'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2014'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:15:32

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:17:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Oct 2020 16:17:38
Data point term sent to Coder	System	27 Oct 2020 16:16:56
User entered 'VITAMIN E'	Brenda Miller (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Miller (b) (4)	01 Nov 2020 15:09:46
User entered 'No (N)'	Brenda Miller (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'SUPPLEMENT'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '268'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2014'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:16:07

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:15:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: ASENAPINE MALEATE, PRODUCTSYNONYM: SAPHRIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:19:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 16:19:42
Data point term sent to Coder	System	27 Oct 2020 16:19:01
User entered 'SAPHRIS'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:15:49
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:15:48
User entered 'BIPOLAR DISORDER'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:15:52
User entered '10'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:09
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:10
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:12
User entered 'twice daily (BID)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:13
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:19
User entered 'Oral (ORAL)'	Brenda Miller (b) (4)	27 Oct 2020 16:18:16
	(b) (4)	

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:24
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:26
User entered '15 Jul 2013'	Brenda Miller (b) (4)	27 Oct 2020 16:18:16
	(b) (4)	

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:36
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:38
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:39
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:16:44
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:18:16

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIGLAUCOMA PREPARATIONS AND MIOTICS, ATC: BETA BLOCKING AGENTS, PRODUCT: TIMOLOL MALEATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:25:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:25:21
Data point term sent to Coder	System	27 Oct 2020 16:22:05
User entered 'TIMOLOL MALEATE'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'GLAUCOMA'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'gtts'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered 'OU'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2010'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 16:21:30

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: SODIUM BICARBONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:45:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 14:45:20
Data point term sent to Coder	System	05 Nov 2020 14:23:48
User entered 'SODIUM BICARBONATE'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
User entered 'CHRONIC RENAL DISEASE'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '250'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
User entered '15 Jul 2015'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 14:23:27

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: RISPERIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 17:12:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Nov 2020 17:12:32
Data point term sent to Coder	System	08 Nov 2020 17:11:34
User entered 'RISPERIDONE'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:08
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:10
User entered 'BIPOLAR DISORDER'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:12
User entered '1'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:13
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:15
User entered empty.	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:17
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:25
User entered empty.	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:27
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:29
User entered empty.	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:30
User entered '04 Nov 2020'	Brenda Miller (b) (4)	08 Nov 2020 17:10:39
	(b) (4)	

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:32
User entered '0'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:34
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:36
User entered empty.	Brenda Miller (b) (4)	08 Nov 2020 17:10:39
	(b) (4)	

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 17:09:38
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:09:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Nov 2020 17:10:39

US3662181

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:09:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	27 Oct 2020 16:22:06

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'USA-US088-2020-MRNA-1273-P301000003'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Carl'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Fichtenbaum'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '231 Albert Sabin Way'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Cincinnati'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered '200 Albert Sabin Way Cincinnati, OH'	michelle saemann (b) (4)	04 Nov 2020 21:19:04
	(b) (4)	

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '45267'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered 'US'	System	04 Nov 2020 15:08:04

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 15:08:04

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'USA-US088-2020-MRNA-1273-P301000003'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Yes (Y)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'No (N)'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Carl'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Fichtenbaum'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '231 Albert Sabin Way'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered 'Cincinnati'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered '200 Albert Sabin Way Cincinnati, OH'	michelle saemann (b) (4)	04 Nov 2020 21:19:04
	(b) (4)	

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:07:57
User entered '45267'	System	04 Nov 2020 15:07:33

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered 'US'	System	04 Nov 2020 15:08:04

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 11:09:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 15:08:04

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:02

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 16:45:19
User entered '04/Nov/2020 15:08'	System	04 Nov 2020 15:08:04

US3662181

Folder: SAE USA-US088-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:09:02

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)	09 Nov 2020 16:45:19
User entered '1'	(b) (4), (b) (6)	04 Nov 2020 15:08:04