

US3342281 (Prod: Tekton Research- Austin)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:57:19

All time stamps listed in this document are displayed in GMT

US3342281

Form: Participant Creation

Generated On: 26 Nov 2020 10:57:19

[Participant ID](#)

US3342281

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

US3342281

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	42
Age Units	YEARS
Age (Derived)	42
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	LATINO
Unknown	False
Not reported	False

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3342281

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:57:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3342281

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:57:19

Were any significant conditions reported?

Yes ☒

No ☐

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN MAR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

Condition	PRE-DIABETES MELLITUS TYPE 2
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	09:42 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:42
Height (<i>xxx.x</i>)	165.0 cm
Weight (<i>xxx.x</i>)	79.6 kg
BMI (<i>xxx.x</i>)	29.23783 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342281

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3342281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:19

What was the date of randomization? (dd MMM yyyy) 24 SEP 2020

What was the participant's randomization number? 115482

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 ☒

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:19

Height	
Weight	

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

Height	
Weight	
Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	09:42 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 09:42
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

Height	
Weight	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	11:42 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 11:42
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3342281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

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.

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	24 SEP 2020
What was the treatment time? (00:00-23:59)	11:11 (24 HR)
Treatment Date and Time (derived)	24 SEP 2020 11:11
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3342281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	24 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:29 (24 HR)
Collection date and time (derived)	24 SEP 2020 10:29

US3342281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:19

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:31	24 SEP 2020 10:31
Nasopharyngeal Swab 2	No		

US3342281

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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

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

24 SEP 2020 11:45

PC Open Date & Time

24 SEP 2020 11:31

PC Close Date & Time

24 SEP 2020 14:01

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 18:22

PC Open Date & Time

24 SEP 2020 14:56

PC Close Date & Time

25 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

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

25 SEP 2020 18:00

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

26 SEP 2020 23:01

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 23:11

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 08:33

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

30 SEP 2020 01:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

01 OCT 2020 00:00

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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

24 SEP 2020 11:46

PC Open Date & Time

24 SEP 2020 11:31

PC Close Date & Time

24 SEP 2020 14:01

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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

24 SEP 2020 18:23

PC Open Date & Time

24 SEP 2020 14:56

PC Close Date & Time

25 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

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

25 SEP 2020 18:02

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

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

26 SEP 2020 23:01

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

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

27 SEP 2020 23:12

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

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

29 SEP 2020 08:33

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 01:33

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 00:01

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 11:46
PC Open Date & Time	24 SEP 2020 11:31
PC Close Date & Time	24 SEP 2020 14:01

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 18:24
PC Open Date & Time	24 SEP 2020 14:56
PC Close Date & Time	25 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:02
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 23:01
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 23:12
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 08:34
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 01:34
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 00:02
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 02 OCT 2020 11:52

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3342281

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 OCT 2020 11:52
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3342281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

Was Contact Attempted?

Yes ☒

No ☐

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

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342281

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

Was Contact Attempted?

Yes ☒

No ☐

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

09 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342281

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

Was Contact Attempted?

Yes ☒

No ☐

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

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342281

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	13:24 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 13:24
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	14:37 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 14:37
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3342281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	27 OCT 2020
What was the treatment time? (00:00-23:59)	13:57 (24 HR)
Treatment Date and Time (derived)	27 OCT 2020 13:57
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3342281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	27 OCT 2020
Collection time (<i>00:00-23:59</i>)	13:40 (24 HR)
Collection date and time (derived)	27 OCT 2020 13:40

US3342281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:19

Collection date (dd MMM yyyy)			27 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:42	27 OCT 2020 13:42
Nasopharyngeal Swab 2	No		

US3342281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 14:45

PC Open Date & Time

27 OCT 2020 14:17

PC Close Date & Time

27 OCT 2020 16:47

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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 95.0 °F

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

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

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

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

PC Time Stamp 28 OCT 2020 00:49

PC Open Date & Time 27 OCT 2020 17:42

PC Close Date & Time 28 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	False
To PREVENT pain or fever from occurring	True
PC Time Stamp	28 OCT 2020 17:00
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

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

97.6 °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

29 OCT 2020 16:27

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

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

97.0 °F

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

Yes ☒

No ☐

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

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

31 OCT 2020 09:22

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 NOV 2020 01:20

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 NOV 2020 22:11

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

02 NOV 2020 17:59

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 14:45

PC Open Date & Time

27 OCT 2020 14:17

PC Close Date & Time

27 OCT 2020 16:47

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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

28 OCT 2020 00:50

PC Open Date & Time

27 OCT 2020 17:42

PC Close Date & Time

28 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

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

28 OCT 2020 17:00

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

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

29 OCT 2020 16:28

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

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

31 OCT 2020 09:23

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

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

01 NOV 2020 01:20

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 NOV 2020 22:11

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 17:59

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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

No ☒

Yes ☐

PC Time stamp	27 OCT 2020 14:47
PC Open Date & Time	27 OCT 2020 14:17
PC Close Date & Time	27 OCT 2020 16:47

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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

No ☒

Yes ☐

PC Time stamp	28 OCT 2020 00:51
PC Open Date & Time	27 OCT 2020 17:42
PC Close Date & Time	28 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 17:01
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 16:28
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

	Yes <input type="checkbox"/>
PC Time stamp	31 OCT 2020 09:24
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 01:21
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 22:12
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

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 ☒

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 18:00
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3342281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

Was Contact Attempted?

Yes ☒

No ☐

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

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342281

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

Was Contact Attempted?

Yes ☒

No ☐

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

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342281

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

Was Contact Attempted?

Yes ☒

No ☐

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

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3342281

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:25 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 10:25
Temperature (<i>xxx.x</i>)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	72 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3342281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3342281

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3342281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 10:50:10
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

13 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 MAY 2021 00:01
Patient Cloud Close Date & Time	26 MAY 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 JUN 2021 00:01
Patient Cloud Close Date & Time	16 JUN 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 JUN 2021 00:01
Patient Cloud Close Date & Time	23 JUN 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 SEP 2021 00:01
Patient Cloud Close Date & Time	15 SEP 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Patient Cloud Open Date & Time	09 OCT 2021 00:01
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Patient Cloud Close Date & Time	13 OCT 2021 23:59
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US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Patient Cloud Open Date & Time	23 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JAN 2022 00:01
Patient Cloud Close Date & Time	12 JAN 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 APR 2022 00:01
Patient Cloud Close Date & Time	06 APR 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 JUN 2022 00:01
Patient Cloud Close Date & Time	08 JUN 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 JUN 2022 00:01
Patient Cloud Close Date & Time	22 JUN 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2022 00:01
Patient Cloud Close Date & Time	17 AUG 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Patient Cloud Open Date & Time	27 AUG 2022 00:01
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Patient Cloud Close Date & Time	31 AUG 2022 23:59
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US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 SEP 2022 00:01
Patient Cloud Close Date & Time	14 SEP 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2022 00:01
Patient Cloud Close Date & Time	28 SEP 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 NOV 2022 00:01
Patient Cloud Close Date & Time	09 NOV 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2022 00:01
Patient Cloud Close Date & Time	16 NOV 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Date and time of submission	
Patient Cloud Open Date & Time	19 NOV 2022 00:01
Patient Cloud Close Date & Time	23 NOV 2022 23:59

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2022 00:01
Patient Cloud Close Date & Time	30 NOV 2022 23:59

US3342281

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3342281

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:57:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3342281

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:57:19

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

AEID	
Adverse event	PITYRIASIS ROSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

331 of 1694

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

AEID	USA-US203-2020-MRNA-1273-P30 1000004
Adverse event	CONCUSSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 OCT 2020
Start time (00:00-23:59)	04:30 (24 HR)
AE start date and time (derived)	27 OCT 2020 04:30
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 NOV 2020
End time (00:00-23:59)	10:00 (24 HR)
AE End Date and Time (derived)	20 NOV 2020 10:00
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

v6.020 DTW (1102)

333 of 1694

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

PATIENT REPORTED A HEAD
TRAUMA AS A RESULT OF
PHYSICAL BATTERY ON
27OCT2020 AT 04:30. BY
29OCT2020 THE PATIENT WAS
IN A LOT OF PAIN AND
DECIDED TO GO TO THE
HOSPITAL. HE WAS ADMITTED
FOR ONE NIGHT. TWO SCANS
WERE PREFORMED. PATIENT
REPORTED BLEEDING ON THE
LEFT SIDE OF HIS BRAIN.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

AEID	
Adverse event	LACERATION LEFT UPPER LIP
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 OCT 2020
Start time (00:00-23:59)	04:30 (24 HR)
AE start date and time (derived)	27 OCT 2020 04:30
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 OCT 2020
End time (00:00-23:59)	12:00 (24 HR)
AE End Date and Time (derived)	29 OCT 2020 12:00
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

336 of 1694

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:57:19

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

Yes ☒

No ☐

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

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

Name of Medication	LORATADINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (<i>dd MMM yyyy</i>)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (<i>dd MMM yyyy</i>) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

Name of Medication	MAGNESIUM HYDROXIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	NAUSEA/VOMITING
Dose per administration	2400
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

Name of Medication	HYDROCORTISONE TOPICAL 1%
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CONTACT DERMATITIS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	APPLICATION
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input checked="" type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CONCUSSION: AE
Dose per administration	1000
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

Name of Medication	LEVETIRACETAM
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CONCUSSION: AE
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

Name of Medication	METHOCARBAMOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CONCUSSION: AE
Dose per administration	750
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		30 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		07 NOV 2020
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)		802 <input type="checkbox"/>
		803 <input type="checkbox"/>
		804 <input type="checkbox"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	HEADACHE: AR AFTER VACCINE #2
Dose per administration	1000
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3342281

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:57:19

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3342281

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:57:19

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

US3342281

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:57:19

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 ☐

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

SAEID	USA-US203-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:57:19

SAEID	USA-US203-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/NOV/2020 10:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:57:19

SAEID	USA-US203-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	18/NOV/2020 09:57
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

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:57:19

SAEID	USA-US203-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	
Investigator's Last Name	
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	24/NOV/2020 15:29
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

US3342281 (Prod: Tekton Research- Austin)

US3342281

Form: Participant Creation

Generated On: 26 Nov 2020 10:57:19

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3342281'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	24 Sep 2020 14:24:43

US3342281

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:55
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:22:34

US3342281

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:55
User entered '24 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:24:45

US3342281

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:55
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:22:34

US3342281

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	24 Sep 2020 15:22:34

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered (b) (6) 1977'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:24:46

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered '42'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '42'	System	24 Sep 2020 15:23:39

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered 'Male (M)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

White

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered 'I'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

If race is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User closed query 'Per CDM: According to CCGs page 21, only races that the subject self-identifies should be recorded under "Other" field. Please clarify which race is referring as "NOT WHITE". ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:24:16
Query 'Per CDM: According to CCGs page 21, only races that the subject self-identifies should be recorded under "Other" field. Please clarify which race is referring as "NOT WHITE". ' answered with 'patient is of latino race' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 22:17:13
User entered 'LATINO' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 22:16:49
User opened query 'Per CDM: According to CCGs page 21, only races that the subject self-identifies should be recorded under "Other" field. Please clarify which race is referring as "NOT WHITE". ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 21:51:46
User entered 'Latino/Hispanic, not White.'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:57:19

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:14
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:09

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:21
User entered '24 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:39

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	24 Sep 2020 15:23:39

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '2020'	System	24 Sep 2020 15:23:39

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:21
User entered 'Amendment 3 (3)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:39

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:21
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:39

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:21
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:39

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:21
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:39

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:21
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:39

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:21
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 14:24:45

US3342281

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:57:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 15:23:47

US3342281

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:27
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:47

US3342281

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:57:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:33
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:23:55

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
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) (b) (4)	24 Sep 2020 15:51:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:51:57
Data point term sent to Coder	System	24 Sep 2020 15:51:33
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	24 Sep 2020 15:51:24

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered 'UN Mar 2020'	(b) (4), (b) (6)	24 Sep 2020 15:51:24

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 15:51:24

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:51:24

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:51:24

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 15:51:24

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered 'Mar 2020'	System	24 Sep 2020 15:51:24

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '2020'	System	24 Sep 2020 15:51:24

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:51:24

US3342281

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:51:24

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:53:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:53:49
Data point term sent to Coder	System	24 Sep 2020 15:52:36
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	24 Sep 2020 15:52:09

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered 'UN UNK 2010'	(b) (4), (b) (6)	24 Sep 2020 15:52:09

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 15:52:09

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:52:09

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:52:09

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 15:52:09

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	24 Sep 2020 15:52:09

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '2010'	System	24 Sep 2020 15:52:09

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:52:09

US3342281

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:52:09

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 08:07:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 08:07:17
Data point term sent to Coder	System	24 Sep 2020 15:53:38
User entered 'Pre-Diabetes Mellitus Type 2'	(b) (4), (b) (6)	24 Sep 2020 15:52:55

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered 'UN UNK 2012'	(b) (4), (b) (6)	24 Sep 2020 15:52:55

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 15:52:55

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:52:55

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered 'UN UNK 2013'	(b) (4), (b) (6)	24 Sep 2020 15:52:55

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:09
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 15:52:55

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	24 Sep 2020 15:52:55

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '2012'	System	24 Sep 2020 15:52:55

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	24 Sep 2020 15:52:55

US3342281

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '2013'	System	24 Sep 2020 15:52:55

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered '09:42'	(b) (4), (b) (6)	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 09:42'	System	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered '165.0' cm	(b) (4), (b) (6)	24 Sep 2020 15:47:37
DataPoint set to visible.	System	24 Sep 2020 15:23:47

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Sep 2020 15:47:47
User entered '79.6' kg reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 15:47:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Sep 2020 15:47:37
User entered '79.6' (non-conformant).	(b) (4), (b) (6)	24 Sep 2020 15:47:37
DataPoint set to visible.	System	24 Sep 2020 15:23:47

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '29.23783'	System	24 Sep 2020 15:47:47
User entered empty.	System	24 Sep 2020 15:47:37
DataPoint set to visible.	System	24 Sep 2020 15:23:47

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	24 Sep 2020 15:47:47
User entered empty.	System	24 Sep 2020 15:47:37
DataPoint set to visible.	System	24 Sep 2020 15:23:47

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:17:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 15:47:37

US3342281

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:18:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:48:01

US3342281

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:18:49
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 15:48:01

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'No (N)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered 'I'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:57:19

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:36
User entered empty.	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:12

US3342281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:46
User entered 'Yes (Y)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:24

US3342281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:46
User entered '24 Sep 2020'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:24

US3342281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:19:46
User entered 'Clinic (Clinic)'	Darrell O'Brien (b) (4) (b) (4)	24 Sep 2020 15:28:24

US3342281

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	24 Sep 2020 15:28:24

US3342281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:02
User entered '24 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 15:24:47

US3342281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:02
User entered '115482'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 15:24:47

US3342281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:02
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Sep 2020 15:24:47

US3342281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:48:18

US3342281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:48:18

US3342281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:48:18

US3342281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:48:18

US3342281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:19

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:48:18

US3342281

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:02
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:48:18
DataPoint set to visible.	System	24 Sep 2020 15:23:39

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:19

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:19

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:19

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:19

Weight

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered '09:42'	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 09:42'	System	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered '98.0' F	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered '67'	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered '14'	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered '112'	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered '65'	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:19

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:57:19

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 16:35:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 16:35:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:35:50
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 15:49:19
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered '24 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:35:50
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User closed query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:51:27
Query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' answered with 'Post dose time was entered in error originally. It has been corrected.' (Site from DM).	Tiffany Lemuz (b) (4)	30 Sep 2020 22:03:56
User entered '11:42' reason for change: Data Entry Error	Tiffany Lemuz (b) (4)	30 Sep 2020 22:01:39
User opened query 'Per CDM: Time difference between dosing and post-dose vital signs assessment is less than 30 minutes. According to protocol, post-dose vital signs should be measured at least 30 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 18:07:18
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:44:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Sep 2020 16:44:19
User entered '11:12' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:44:19
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:35:50
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:42'	System	30 Sep 2020 22:01:39
User entered '24 Sep 2020 11:12'	System	24 Sep 2020 16:44:19
User entered empty.	System	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:44:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Sep 2020 16:44:19
User entered '96.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:44:19
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:35:50
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:44:19
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:44:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Sep 2020 16:44:19
User entered '59' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:44:19
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:35:50
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Sep 2020 16:44:19
User entered empty.	System	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:44:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Sep 2020 16:44:19
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:44:19
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:35:50
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Sep 2020 16:44:19
User entered empty.	System	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:44:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Sep 2020 16:44:19
User entered '108' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:44:19
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:35:50
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 16:44:19
User entered empty.	System	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:17
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:44:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Sep 2020 16:44:19
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:44:19
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:35:50
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 16:44:19
User entered empty.	System	24 Sep 2020 15:49:19

US3342281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:25
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:49:27

US3342281

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:25
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:49:27

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:20:36

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:58
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:36

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:58
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:36

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 16:20:36

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:58
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:20:36

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:58
User entered '11:11'	(b) (4), (b) (6)	24 Sep 2020 16:20:36

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:11'	System	24 Sep 2020 16:20:36

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:58
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	24 Sep 2020 16:20:36

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:21:58
User entered 'ONCE'	System	24 Sep 2020 16:20:36

US3342281

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 16:20:36

US3342281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:23:49
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	25 Sep 2020 22:19:41

US3342281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24SEP2020 is recorded under Visit 1 Day 1 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable, else clarify. ' answered with 'unscheduled kit was used in place of kit A due to shortage' (Site from DM).	Eileen Euperio (b) (4)	12 Nov 2020 20:05:31
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:23:49
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 24SEP2020 is recorded under Visit 1 Day 1 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable, else clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:26:27
User entered '24 Sep 2020'	Morgan Schulle (b) (4) (b) (4)	25 Sep 2020 22:19:41

US3342281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:23:49
User entered '10:29'	Morgan Schulle (b) (4) (b) (4)	25 Sep 2020 22:19:41

US3342281

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 10:29'	System	25 Sep 2020 22:19:41

US3342281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 24SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 10:30:52
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 24SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'unscheduled kit was used in place of kit A due to shortage' (Site from DM).	Eileen Euperio (b) (4)	12 Nov 2020 20:05:39
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:24:37
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 24SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:08:07
User entered '24 Sep 2020'	Morgan Schulle (b) (4)	25 Sep 2020 22:19:30

US3342281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	25 Sep 2020 22:19:30

US3342281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:24:37
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	25 Sep 2020 22:19:30

US3342281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:24:37
User entered '10:31'	Morgan Schulle (b) (4) (b) (4)	25 Sep 2020 22:19:30

US3342281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '24 Sep 2020 10:31'	System	25 Sep 2020 22:19:30

US3342281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4)	25 Sep 2020 22:19:30

US3342281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:24:37
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	25 Sep 2020 22:19:30

US3342281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:24:37
User entered empty.	Morgan Schulle (b) (4) (b) (4)	25 Sep 2020 22:19:30

US3342281

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 22:19:30

US3342281

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:24:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:20:43

US3342281

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:20:43

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:44:56', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '55bcc499-7c95-430e-9998-9d8a471cafee'	System	24 Sep 2020 16:45:26
User entered 'Yes (Y)'	System	24 Sep 2020 16:45:26

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:45:05', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '55bcc499-7c95-430e-9998-9d8a471cafee' User entered '96.9'	System	24 Sep 2020 16:45:26

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:45:15', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '55bcc499-7c95-430e-9998-9d8a471cafee'	System	24 Sep 2020 16:45:26
User entered 'No (N)'	System	24 Sep 2020 16:45:26

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:45:23', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '55bcc499-7c95-430e-9998-9d8a471cafee' User entered '24 Sep 2020 11:45'	System	24 Sep 2020 16:45:26
	System	24 Sep 2020 16:45:26

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:31'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:01'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:22:37', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c93163b5-cc6f-483c-b5ab-8bbb621d7d16'	System	24 Sep 2020 23:22:58
User entered 'Yes (Y)'	System	24 Sep 2020 23:22:58

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:22:45', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c93163b5-cc6f-483c-b5ab-8bbb621d7d16'	System	24 Sep 2020 23:22:58
User entered '98.6'	System	24 Sep 2020 23:22:58

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:22:49', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c93163b5-cc6f-483c-b5ab-8bbb621d7d16'	System	24 Sep 2020 23:22:58
User entered 'No (N)'	System	24 Sep 2020 23:22:58

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:22:54', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c93163b5-cc6f-483c-b5ab-8bbb621d7d16'	System	24 Sep 2020 23:22:58
User entered '24 Sep 2020 18:22'	System	24 Sep 2020 23:22:58

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:56'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 2'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:00:30', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '1e7814dd-4c55-4b33-84c3-a5d6476f51ee'	System	25 Sep 2020 23:00:50
User entered 'Yes (Y)'	System	25 Sep 2020 23:00:50

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:00:36', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '1e7814dd-4c55-4b33-84c3-a5d6476f51ee'	System	25 Sep 2020 23:00:50
User entered '98.2'	System	25 Sep 2020 23:00:50

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:00:40', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '1e7814dd-4c55-4b33-84c3-a5d6476f51ee'	System	25 Sep 2020 23:00:50
User entered 'No (N)'	System	25 Sep 2020 23:00:50

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:00:45', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '1e7814dd-4c55-4b33-84c3-a5d6476f51ee' User entered '25 Sep 2020 18:00'	System	25 Sep 2020 23:00:50
	System	25 Sep 2020 23:00:50

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 3'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:00:45', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ad4e19d1-99ce-4518-b5bc-40789bd84edd'	System	27 Sep 2020 04:02:08
User entered 'Yes (Y)'	System	27 Sep 2020 04:02:08

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:00:52', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ad4e19d1-99ce-4518-b5bc-40789bd84edd'	System	27 Sep 2020 04:02:08
User entered '98.5'	System	27 Sep 2020 04:02:08

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:00:55', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ad4e19d1-99ce-4518-b5bc-40789bd84edd'	System	27 Sep 2020 04:02:08
User entered 'No (N)'	System	27 Sep 2020 04:02:08

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:00', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ad4e19d1-99ce-4518-b5bc-40789bd84edd' User entered '26 Sep 2020 23:01'	System	27 Sep 2020 04:02:08

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 4'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:11:03', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '37f24860-7de7-4336-9483-a22ee6b371ff'	System	28 Sep 2020 04:11:29
User entered 'Yes (Y)'	System	28 Sep 2020 04:11:29

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:11:16', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '37f24860-7de7-4336-9483-a22ee6b371ff'	System	28 Sep 2020 04:11:29
User entered '98.1'	System	28 Sep 2020 04:11:29

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:11:19', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '37f24860-7de7-4336-9483-a22ee6b371ff'	System	28 Sep 2020 04:11:29
User entered 'No (N)'	System	28 Sep 2020 04:11:29

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:11:25', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '37f24860-7de7-4336-9483-a22ee6b371ff'	System	28 Sep 2020 04:11:29
User entered '27 Sep 2020 23:11'	System	28 Sep 2020 04:11:29

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 5'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:32:44', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '2990811b-4e1f-4b77-b1f5-e5648a31f37b'	System	29 Sep 2020 13:33:10
User entered 'Yes (Y)'	System	29 Sep 2020 13:33:10

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:32:54', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '2990811b-4e1f-4b77-b1f5-e5648a31f37b'	System	29 Sep 2020 13:33:10
User entered '98.4'	System	29 Sep 2020 13:33:10

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:32:59', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '2990811b-4e1f-4b77-b1f5-e5648a31f37b'	System	29 Sep 2020 13:33:10
User entered 'No (N)'	System	29 Sep 2020 13:33:10

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:06', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '2990811b-4e1f-4b77-b1f5-e5648a31f37b'	System	29 Sep 2020 13:33:10
User entered '29 Sep 2020 08:33'	System	29 Sep 2020 13:33:10

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 6'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:32:41', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '04d9993d-0b61-4824-a06c-a53177953f35'	System	30 Sep 2020 06:32:59
User entered 'Yes (Y)'	System	30 Sep 2020 06:32:59

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:32:49', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '04d9993d-0b61-4824-a06c-a53177953f35'	System	30 Sep 2020 06:32:59
User entered '97.9'	System	30 Sep 2020 06:32:59

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:32:52', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '04d9993d-0b61-4824-a06c-a53177953f35'	System	30 Sep 2020 06:32:59
User entered 'No (N)'	System	30 Sep 2020 06:32:59

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:32:57', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '04d9993d-0b61-4824-a06c-a53177953f35'	System	30 Sep 2020 06:32:59
User entered '30 Sep 2020 01:32'	System	30 Sep 2020 06:32:59

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 7'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T23:59:25', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ff45a712-5eb2-4bf8-87e0-5dd557d11255'	System	01 Oct 2020 05:00:20
User entered 'Yes (Y)'	System	01 Oct 2020 05:00:20

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T23:59:30', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ff45a712-5eb2-4bf8-87e0-5dd557d11255'	System	01 Oct 2020 05:00:20
User entered '98.2'	System	01 Oct 2020 05:00:20

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:00:10', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ff45a712-5eb2-4bf8-87e0-5dd557d11255'	System	01 Oct 2020 05:00:20
User entered 'No (N)'	System	01 Oct 2020 05:00:20

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:00:17', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ff45a712-5eb2-4bf8-87e0-5dd557d11255'	System	01 Oct 2020 05:00:20
User entered '01 Oct 2020 00:00'	System	01 Oct 2020 05:00:20

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:45:53', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fbcdfce9-6122-40df-9a97-7f1e6c4098cb'	System	24 Sep 2020 16:46:16
User entered 'None (1)'	System	24 Sep 2020 16:46:16

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:00', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fbcdfce9-6122-40df-9a97-7f1e6c4098cb'	System	24 Sep 2020 16:46:16
User entered 'No (N)'	System	24 Sep 2020 16:46:16

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:04', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fbcdfce9-6122-40df-9a97-7f1e6c4098cb'	System	24 Sep 2020 16:46:16
User entered 'No (N)'	System	24 Sep 2020 16:46:16

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:10', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fbcdfce9-6122-40df-9a97-7f1e6c4098cb' User entered 'None (1)'	System	24 Sep 2020 16:46:16

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:15', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fbcdfce9-6122-40df-9a97-7f1e6c4098cb' User entered '24 Sep 2020 11:46'	System	24 Sep 2020 16:46:16
	System	24 Sep 2020 16:46:16

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:31'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:01'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:09', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5d1212e9-5a07-47db-ae08-30e7e1bd6668'	System	24 Sep 2020 23:23:33
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 23:23:33

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:12', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5d1212e9-5a07-47db-ae08-30e7e1bd6668'	System	24 Sep 2020 23:23:33
User entered 'No (N)'	System	24 Sep 2020 23:23:33

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:21', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5d1212e9-5a07-47db-ae08-30e7e1bd6668'	System	24 Sep 2020 23:23:33
User entered 'No (N)'	System	24 Sep 2020 23:23:33

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:26', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5d1212e9-5a07-47db-ae08-30e7e1bd6668'	System	24 Sep 2020 23:23:33
User entered 'None (1)'	System	24 Sep 2020 23:23:33

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:29', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5d1212e9-5a07-47db-ae08-30e7e1bd6668'	System	24 Sep 2020 23:23:33
User entered '24 Sep 2020 18:23'	System	24 Sep 2020 23:23:33

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:56'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 2'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:00:53', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9f612550-e7cd-48fe-aaac-e1ebafd03a2f'	System	25 Sep 2020 23:02:09
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 23:02:09

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:01:36', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9f612550-e7cd-48fe-aaac-e1ebafd03a2f'	System	25 Sep 2020 23:02:09
User entered 'No (N)'	System	25 Sep 2020 23:02:09

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:01:43', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9f612550-e7cd-48fe-aaac-e1ebafd03a2f'	System	25 Sep 2020 23:02:09
User entered 'No (N)'	System	25 Sep 2020 23:02:09

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:02:01', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9f612550-e7cd-48fe-aaac-e1ebafd03a2f'	System	25 Sep 2020 23:02:09
User entered 'None (1)'	System	25 Sep 2020 23:02:09

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:02:04', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9f612550-e7cd-48fe-aaac-e1ebafd03a2f' User entered '25 Sep 2020 18:02'	System	25 Sep 2020 23:02:09
	System	25 Sep 2020 23:02:09

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 3'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:11', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '22931f5c-493c-4658-8869-5641857b7e76'	System	27 Sep 2020 04:02:38
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 04:02:38

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:14', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '22931f5c-493c-4658-8869-5641857b7e76'	System	27 Sep 2020 04:02:38
User entered 'No (N)'	System	27 Sep 2020 04:02:38

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:18', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '22931f5c-493c-4658-8869-5641857b7e76'	System	27 Sep 2020 04:02:38
User entered 'No (N)'	System	27 Sep 2020 04:02:38

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:28', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '22931f5c-493c-4658-8869-5641857b7e76'	System	27 Sep 2020 04:02:38
User entered 'None (1)'	System	27 Sep 2020 04:02:38

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:30', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '22931f5c-493c-4658-8869-5641857b7e76'	System	27 Sep 2020 04:02:38
User entered '26 Sep 2020 23:01'	System	27 Sep 2020 04:02:38

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 4'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:11:43', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'f1206041-34fc-42ac-a780-1f52e54cc449'	System	28 Sep 2020 04:12:24
User entered 'None (1)'	System	28 Sep 2020 04:12:24

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:11:47', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'f1206041-34fc-42ac-a780-1f52e54cc449'	System	28 Sep 2020 04:12:24
User entered 'No (N)'	System	28 Sep 2020 04:12:24

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:11:53', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'f1206041-34fc-42ac-a780-1f52e54cc449'	System	28 Sep 2020 04:12:24
User entered 'No (N)'	System	28 Sep 2020 04:12:24

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:12:10', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'f1206041-34fc-42ac-a780-1f52e54cc449'	System	28 Sep 2020 04:12:24
User entered 'None (1)'	System	28 Sep 2020 04:12:24

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:12:21', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'f1206041-34fc-42ac-a780-1f52e54cc449'	System	28 Sep 2020 04:12:24
User entered '27 Sep 2020 23:12'	System	28 Sep 2020 04:12:24

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 5'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:12', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6b1838e5-bc87-4df5-a236-ec81e51544cb' User entered 'None (1)'	System	29 Sep 2020 13:33:43

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:16', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6b1838e5-bc87-4df5-a236-ec81e51544cb'	System	29 Sep 2020 13:33:43
User entered 'No (N)'	System	29 Sep 2020 13:33:43

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:28', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6b1838e5-bc87-4df5-a236-ec81e51544cb' User entered 'No (N)'	System	29 Sep 2020 13:33:43

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:36', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6b1838e5-bc87-4df5-a236-ec81e51544cb' User entered 'None (1)'	System	29 Sep 2020 13:33:43

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:39', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6b1838e5-bc87-4df5-a236-ec81e51544cb' User entered '29 Sep 2020 08:33'	System	29 Sep 2020 13:33:43
	System	29 Sep 2020 13:33:43

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 6'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:07', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '802222a4-bfaa-4ea9-b904-0d486f0b2d38'	System	30 Sep 2020 06:33:43
User entered 'None (1)'	System	30 Sep 2020 06:33:43

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:15', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '802222a4-bfaa-4ea9-b904-0d486f0b2d38'	System	30 Sep 2020 06:33:43
User entered 'No (N)'	System	30 Sep 2020 06:33:43

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:19', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '802222a4-bfaa-4ea9-b904-0d486f0b2d38'	System	30 Sep 2020 06:33:43
User entered 'No (N)'	System	30 Sep 2020 06:33:43

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:38', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '802222a4-bfaa-4ea9-b904-0d486f0b2d38'	System	30 Sep 2020 06:33:43
User entered 'None (1)'	System	30 Sep 2020 06:33:43

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:40', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '802222a4-bfaa-4ea9-b904-0d486f0b2d38' User entered '30 Sep 2020 01:33'	System	30 Sep 2020 06:33:43
	System	30 Sep 2020 06:33:43

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 7'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:00:34', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '1458e76b-068f-4579-b34b-0ad367c6e56c'	System	01 Oct 2020 05:01:16
User entered 'None (1)'	System	01 Oct 2020 05:01:16

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:01:00', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '1458e76b-068f-4579-b34b-0ad367c6e56c'	System	01 Oct 2020 05:01:16
User entered 'No (N)'	System	01 Oct 2020 05:01:16

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:01:03', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '1458e76b-068f-4579-b34b-0ad367c6e56c'	System	01 Oct 2020 05:01:16
User entered 'No (N)'	System	01 Oct 2020 05:01:16

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:01:07', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '1458e76b-068f-4579-b34b-0ad367c6e56c'	System	01 Oct 2020 05:01:16
User entered 'None (1)'	System	01 Oct 2020 05:01:16

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:01:13', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '1458e76b-068f-4579-b34b-0ad367c6e56c'	System	01 Oct 2020 05:01:16
User entered '01 Oct 2020 00:01'	System	01 Oct 2020 05:01:16

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:21', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6993d7bc-3a50-4918-a00a-6ea610405352'	System	24 Sep 2020 16:47:01
User entered 'None (0)'	System	24 Sep 2020 16:47:01

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:30', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6993d7bc-3a50-4918-a00a-6ea610405352'	System	24 Sep 2020 16:47:01
User entered 'None (0)'	System	24 Sep 2020 16:47:01

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:38', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6993d7bc-3a50-4918-a00a-6ea610405352'	System	24 Sep 2020 16:47:01
User entered 'None (0)'	System	24 Sep 2020 16:47:01

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:42', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6993d7bc-3a50-4918-a00a-6ea610405352'	System	24 Sep 2020 16:47:01
User entered 'None (0)'	System	24 Sep 2020 16:47:01

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:44', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6993d7bc-3a50-4918-a00a-6ea610405352'	System	24 Sep 2020 16:47:01
User entered 'None (0)'	System	24 Sep 2020 16:47:01

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:47', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6993d7bc-3a50-4918-a00a-6ea610405352'	System	24 Sep 2020 16:47:01
User entered 'None (0)'	System	24 Sep 2020 16:47:01

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:52', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6993d7bc-3a50-4918-a00a-6ea610405352'	System	24 Sep 2020 16:47:01
User entered 'No (N)'	System	24 Sep 2020 16:47:01

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T11:46:59', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6993d7bc-3a50-4918-a00a-6ea610405352'	System	24 Sep 2020 16:47:01
User entered '24 Sep 2020 11:46'	System	24 Sep 2020 16:47:01

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:31'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:01'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:36', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5c5c72ae-27c1-423a-9b41-b6ea4b10fd25'	System	24 Sep 2020 23:24:10
User entered 'None (0)'	System	24 Sep 2020 23:24:10

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:40', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5c5c72ae-27c1-423a-9b41-b6ea4b10fd25'	System	24 Sep 2020 23:24:10
User entered 'None (0)'	System	24 Sep 2020 23:24:10

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:44', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5c5c72ae-27c1-423a-9b41-b6ea4b10fd25'	System	24 Sep 2020 23:24:10
User entered 'None (0)'	System	24 Sep 2020 23:24:10

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:48', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5c5c72ae-27c1-423a-9b41-b6ea4b10fd25'	System	24 Sep 2020 23:24:10
User entered 'None (0)'	System	24 Sep 2020 23:24:10

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:51', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5c5c72ae-27c1-423a-9b41-b6ea4b10fd25'	System	24 Sep 2020 23:24:10
User entered 'None (0)'	System	24 Sep 2020 23:24:10

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:23:56', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5c5c72ae-27c1-423a-9b41-b6ea4b10fd25'	System	24 Sep 2020 23:24:10
User entered 'None (0)'	System	24 Sep 2020 23:24:10

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:24:02', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5c5c72ae-27c1-423a-9b41-b6ea4b10fd25'	System	24 Sep 2020 23:24:10
User entered 'No (N)'	System	24 Sep 2020 23:24:10

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-24T18:24:05', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5c5c72ae-27c1-423a-9b41-b6ea4b10fd25'	System	24 Sep 2020 23:24:10
User entered '24 Sep 2020 18:24'	System	24 Sep 2020 23:24:10

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 14:56'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 2'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:02:11', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c038e9cd-19da-4d11-a216-cd7ff11c60a7'	System	25 Sep 2020 23:03:12
User entered 'None (0)'	System	25 Sep 2020 23:03:12

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:02:19', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c038e9cd-19da-4d11-a216-cd7ff11c60a7'	System	25 Sep 2020 23:03:12
User entered 'None (0)'	System	25 Sep 2020 23:03:12

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:02:24', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c038e9cd-19da-4d11-a216-cd7ff11c60a7'	System	25 Sep 2020 23:03:12
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:03:12

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:02:30', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c038e9cd-19da-4d11-a216-cd7ff11c60a7'	System	25 Sep 2020 23:03:12
User entered 'None (0)'	System	25 Sep 2020 23:03:12

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:02:41', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c038e9cd-19da-4d11-a216-cd7ff11c60a7'	System	25 Sep 2020 23:03:12
User entered 'None (0)'	System	25 Sep 2020 23:03:12

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:02:46', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c038e9cd-19da-4d11-a216-cd7ff11c60a7'	System	25 Sep 2020 23:03:12
User entered 'None (0)'	System	25 Sep 2020 23:03:12

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:02:51', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c038e9cd-19da-4d11-a216-cd7ff11c60a7'	System	25 Sep 2020 23:03:12
User entered 'No (N)'	System	25 Sep 2020 23:03:12

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-25T18:02:54', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c038e9cd-19da-4d11-a216-cd7ff11c60a7' User entered '25 Sep 2020 18:02'	System	25 Sep 2020 23:03:12
	System	25 Sep 2020 23:03:12

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 3'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:34', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11c94e20-bcad-405e-8ef0-66c5b5653052'	System	27 Sep 2020 04:02:41
User entered 'None (0)'	System	27 Sep 2020 04:02:41

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:40', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11c94e20-bcad-405e-8ef0-66c5b5653052'	System	27 Sep 2020 04:02:41
User entered 'None (0)'	System	27 Sep 2020 04:02:41

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:43', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11c94e20-bcad-405e-8ef0-66c5b5653052'	System	27 Sep 2020 04:02:41
User entered 'None (0)'	System	27 Sep 2020 04:02:41

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:45', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11c94e20-bcad-405e-8ef0-66c5b5653052'	System	27 Sep 2020 04:02:41
User entered 'None (0)'	System	27 Sep 2020 04:02:41

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:48', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11c94e20-bcad-405e-8ef0-66c5b5653052'	System	27 Sep 2020 04:02:41
User entered 'None (0)'	System	27 Sep 2020 04:02:41

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:50', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11c94e20-bcad-405e-8ef0-66c5b5653052'	System	27 Sep 2020 04:02:41
User entered 'None (0)'	System	27 Sep 2020 04:02:41

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:56', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11c94e20-bcad-405e-8ef0-66c5b5653052'	System	27 Sep 2020 04:02:41
User entered 'No (N)'	System	27 Sep 2020 04:02:41

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-26T23:01:59', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11c94e20-bcad-405e-8ef0-66c5b5653052'	System	27 Sep 2020 04:02:41
User entered '26 Sep 2020 23:01'	System	27 Sep 2020 04:02:41

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 4'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:12:33', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e51addad-644e-4ef4-a5ff-136ac7076cbe'	System	28 Sep 2020 04:12:54
User entered 'None (0)'	System	28 Sep 2020 04:12:54

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:12:36', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e51addad-644e-4ef4-a5ff-136ac7076cbe'	System	28 Sep 2020 04:12:54
User entered 'None (0)'	System	28 Sep 2020 04:12:54

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:12:39', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e51addad-644e-4ef4-a5ff-136ac7076cbe' User entered 'None (0)'	System	28 Sep 2020 04:12:54

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:12:41', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e51addad-644e-4ef4-a5ff-136ac7076cbe' User entered 'None (0)'	System	28 Sep 2020 04:12:54

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:12:43', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e51addad-644e-4ef4-a5ff-136ac7076cbe'	System	28 Sep 2020 04:12:54
User entered 'None (0)'	System	28 Sep 2020 04:12:54

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:12:45', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e51addad-644e-4ef4-a5ff-136ac7076cbe'	System	28 Sep 2020 04:12:54
User entered 'None (0)'	System	28 Sep 2020 04:12:54

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:12:51', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e51addad-644e-4ef4-a5ff-136ac7076cbe' User entered 'No (N)'	System	28 Sep 2020 04:12:54

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-27T23:12:53', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e51addad-644e-4ef4-a5ff-136ac7076cbe'	System	28 Sep 2020 04:12:54
User entered '27 Sep 2020 23:12'	System	28 Sep 2020 04:12:54

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 5'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:43', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'b31d43f7-32d9-467b-8ab6-c0b0aa5bcb91'	System	29 Sep 2020 13:34:09
User entered 'None (0)'	System	29 Sep 2020 13:34:09

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:46', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'b31d43f7-32d9-467b-8ab6-c0b0aa5bcb91'	System	29 Sep 2020 13:34:09
User entered 'None (0)'	System	29 Sep 2020 13:34:09

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:50', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'b31d43f7-32d9-467b-8ab6-c0b0aa5bcb91'	System	29 Sep 2020 13:34:09
User entered 'None (0)'	System	29 Sep 2020 13:34:09

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:53', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'b31d43f7-32d9-467b-8ab6-c0b0aa5bcb91'	System	29 Sep 2020 13:34:09
User entered 'None (0)'	System	29 Sep 2020 13:34:09

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:55', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'b31d43f7-32d9-467b-8ab6-c0b0aa5bcb91'	System	29 Sep 2020 13:34:09
User entered 'None (0)'	System	29 Sep 2020 13:34:09

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:33:58', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'b31d43f7-32d9-467b-8ab6-c0b0aa5bcb91'	System	29 Sep 2020 13:34:09
User entered 'None (0)'	System	29 Sep 2020 13:34:09

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:34:02', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'b31d43f7-32d9-467b-8ab6-c0b0aa5bcb91'	System	29 Sep 2020 13:34:09
User entered 'No (N)'	System	29 Sep 2020 13:34:09

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-29T08:34:06', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'b31d43f7-32d9-467b-8ab6-c0b0aa5bcb91'	System	29 Sep 2020 13:34:09
User entered '29 Sep 2020 08:34'	System	29 Sep 2020 13:34:09

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 6'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:45', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7014e59-603b-4ef2-9540-4f573bab224a' User entered 'None (0)'	System	30 Sep 2020 06:34:06
	System	30 Sep 2020 06:34:06

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:47', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7014e59-603b-4ef2-9540-4f573bab224a' User entered 'None (0)'	System	30 Sep 2020 06:34:06
	System	30 Sep 2020 06:34:06

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:49', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7014e59-603b-4ef2-9540-4f573bab224a' User entered 'None (0)'	System	30 Sep 2020 06:34:06
	System	30 Sep 2020 06:34:06

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:52', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7014e59-603b-4ef2-9540-4f573bab224a' User entered 'None (0)'	System	30 Sep 2020 06:34:06
	System	30 Sep 2020 06:34:06

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:54', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7014e59-603b-4ef2-9540-4f573bab224a' User entered 'None (0)'	System	30 Sep 2020 06:34:06
	System	30 Sep 2020 06:34:06

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:33:56', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7014e59-603b-4ef2-9540-4f573bab224a' User entered 'None (0)'	System	30 Sep 2020 06:34:06
	System	30 Sep 2020 06:34:06

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:34:02', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7014e59-603b-4ef2-9540-4f573bab224a' User entered 'No (N)'	System	30 Sep 2020 06:34:06

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-09-30T01:34:04', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7014e59-603b-4ef2-9540-4f573bab224a' User entered '30 Sep 2020 01:34'	System	30 Sep 2020 06:34:06
	System	30 Sep 2020 06:34:06

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Sep 2020 16:20:36
User entered 'Day 7'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:01:23', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '189ed3b9-0f71-4ad2-ad8f-62267dffdbff'	System	01 Oct 2020 05:02:32
User entered 'None (0)'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:01:32', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '189ed3b9-0f71-4ad2-ad8f-62267dffdbff'	System	01 Oct 2020 05:02:32
User entered 'No interference with activity (1)'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:01:36', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '189ed3b9-0f71-4ad2-ad8f-62267dffdbff'	System	01 Oct 2020 05:02:32
User entered 'None (0)'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:02:01', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '189ed3b9-0f71-4ad2-ad8f-62267dffdbff'	System	01 Oct 2020 05:02:32
User entered 'None (0)'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:02:06', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '189ed3b9-0f71-4ad2-ad8f-62267dffdbff'	System	01 Oct 2020 05:02:32
User entered 'None (0)'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:02:08', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '189ed3b9-0f71-4ad2-ad8f-62267dffdbff'	System	01 Oct 2020 05:02:32
User entered 'None (0)'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:02:28', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '189ed3b9-0f71-4ad2-ad8f-62267dffdbff'	System	01 Oct 2020 05:02:32
User entered 'No (N)'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-01T00:02:30', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '189ed3b9-0f71-4ad2-ad8f-62267dffdbff'	System	01 Oct 2020 05:02:32
User entered '01 Oct 2020 00:02'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 16:20:36

US3342281

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 05:02:32
User entered 'Day 8'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:57:19

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-02T11:52:19', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e6d5b20a-84e6-4aea-ba13-acfce447ac49'	System	02 Oct 2020 16:52:29
User entered 'None (0)'	System	02 Oct 2020 16:52:29

US3342281

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-02T11:52:27', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e6d5b20a-84e6-4aea-ba13-acfce447ac49'	System	02 Oct 2020 16:52:29
User entered '02 Oct 2020 11:52'	System	02 Oct 2020 16:52:29

US3342281

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 05:02:32
User entered 'Day 8'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:57:19

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 (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-02T11:52:31', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5ff83807-7501-4a4d-b4c8-a7a092a45cfb'	System	02 Oct 2020 16:52:38
User entered 'No (N)'	System	02 Oct 2020 16:52:38

US3342281

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (DE7C870F-31B9-4F4D-9696-5BB659F7A5E1)', Time: '2020-10-02T11:52:34', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5ff83807-7501-4a4d-b4c8-a7a092a45cfb'	System	02 Oct 2020 16:52:38
User entered '02 Oct 2020 11:52'	System	02 Oct 2020 16:52:38

US3342281

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	01 Oct 2020 05:02:32

US3342281

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 05:02:32

US3342281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:26:26
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	01 Oct 2020 21:51:00
	(b) (4)	

US3342281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:26:26
User entered '01 Oct 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 17:00:40
User entered '1 Oct 2020'	Ethan Shotton (b) (4)	01 Oct 2020 21:51:00

US3342281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:26:26
User entered 'Contact Made (CONTACT MADE)'	Ethan Shotton (b) (4) (b) (4)	01 Oct 2020 21:51:00

US3342281

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:26:26
User entered empty.	Ethan Shotton (b) (4)	01 Oct 2020 21:51:00

US3342281

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:26:34
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	01 Oct 2020 21:51:03

US3342281

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Oct 2020 21:51:03

US3342281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:26:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:05:40

US3342281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:26:48
User entered '09 Oct 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 17:00:50
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 14:05:40

US3342281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:26:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 14:05:40

US3342281

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:26:48
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:05:40

US3342281

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:26:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:05:47

US3342281

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Oct 2020 14:05:47

US3342281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:27:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 17:45:23

US3342281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:27:21
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 17:45:23

US3342281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:27:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Oct 2020 17:45:23

US3342281

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:27:21
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 17:45:23

US3342281

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:27:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 17:45:31

US3342281

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Oct 2020 17:45:31

US3342281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:27:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 19:59:20

US3342281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:27:59
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 19:59:20

US3342281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:27:59
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Oct 2020 19:59:20

US3342281

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	27 Oct 2020 19:59:20

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Ethan Shotton (b) (4) (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User entered '27 Oct 2020'	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:50:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Oct 2020 19:50:23
User entered '13:24' reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Oct 2020 19:50:23
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:47:14
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '27 Oct 2020 13:24'	System	27 Oct 2020 19:50:23
User entered empty.	System	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:50:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Oct 2020 19:50:23
User entered '99.0' F reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Oct 2020 19:50:23
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:47:14
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User entered 'Oral (Oral)' reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Oct 2020 19:50:23
User entered empty.	(b) (4)	
	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:50:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Oct 2020 19:50:23
User entered '79' reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Oct 2020 19:50:23
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:47:14
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Oct 2020 19:50:23
User entered empty.	System	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:50:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Oct 2020 19:50:23
User entered '12' reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Oct 2020 19:50:23
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:47:14
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Oct 2020 19:50:23
User entered empty.	System	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:50:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Oct 2020 19:50:23
User entered '112' reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Oct 2020 19:50:23
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:47:14
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 19:50:23
User entered empty.	System	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:50:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Oct 2020 19:50:23
User entered '78' reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Oct 2020 19:50:23
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:47:14
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:57:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 19:50:23
User entered empty.	System	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Ethan Shotton (b) (4) (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User entered '27 Oct 2020'	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User entered '14:37'	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '27 Oct 2020 14:37'	System	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User entered '99.0' F	Ethan Shotton (b) (4) (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User entered 'Oral (Oral)'	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

Pulse (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:59:00
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Oct 2020 19:59:00
User entered '97' reason for change: Data Entry Error	Ethan Shotton (b) (4) (b) (4)	27 Oct 2020 19:59:00
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	27 Oct 2020 19:50:23
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).		27 Oct 2020 19:50:23
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:50:23
User entered empty; reason for change Data Entry Error	Ethan Shotton (b) (4) (b) (4)	27 Oct 2020 19:50:23
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	27 Oct 2020 19:47:14
User entered '16'	Ethan Shotton (b) (4) (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Oct 2020 19:59:00
User entered empty.	System	27 Oct 2020 19:50:23
User entered 'bpm'	System	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:50:23
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Oct 2020 19:50:23
User entered '16' reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Oct 2020 19:50:23
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:47:14
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Oct 2020 19:50:23
User entered empty.	System	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:59:00
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Oct 2020 19:59:00
User entered '121' reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Oct 2020 19:59:00
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:47:14
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 19:59:00
User entered empty.	System	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:59:00
Query 'Data is required. Please provide.' answered by System data change (Site from System).		27 Oct 2020 19:59:00
User entered '85' reason for change: Data Entry Error	Ethan Shotton (b) (4)	27 Oct 2020 19:59:00
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 19:47:14
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:57:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Oct 2020 19:59:00
User entered empty.	System	27 Oct 2020 19:47:14

US3342281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 19:59:46

US3342281

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:11
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 19:59:46

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:18
User entered 'Yes (Y)'	Ethan Shotton (b) (4)	27 Oct 2020 19:29:29
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

If No, reason not given

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:18
User entered empty.	Ethan Shotton (b) (4)	27 Oct 2020 19:29:29
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:18
User entered empty.	Ethan Shotton (b) (4) (b) (4)	27 Oct 2020 19:29:29

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	27 Oct 2020 19:29:29

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:18
User entered '27 Oct 2020'	Ethan Shotton (b) (4)	27 Oct 2020 19:29:29
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:18
User entered '13:57'	Ethan Shotton (b) (4)	27 Oct 2020 19:29:29
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '27 Oct 2020 13:57'	System	27 Oct 2020 19:29:29

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:18
User entered 'Left Arm (LEFT ARM)'	Ethan Shotton (b) (4)	27 Oct 2020 19:29:29

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:28:18
User entered 'ONCE'	System	27 Oct 2020 19:29:29

US3342281

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:57:19

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	27 Oct 2020 19:29:29

US3342281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:29:36
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:44:11

US3342281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 27-OCT-2020. However, collection date is missing in GCL. Please confirm if 27-OCT-2020 is correct date to update in GCL records.' answered with 'can confirm collection was done on 27OCT2020' (Site from DM).	Eileen Euperio (b) (4)	12 Nov 2020 20:06:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 15:29:36
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 27-OCT-2020. However, collection date is missing in GCL. Please confirm if 27-OCT-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:46:57
User entered '27 Oct 2020'	Morgan Schulle (b) (4)	29 Oct 2020 14:44:11
	(b) (4)	

US3342281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:29:36
User entered '13:40'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:44:11

US3342281

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '27 Oct 2020 13:40'	System	29 Oct 2020 14:44:11

US3342281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:57:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:29:50
User entered '27 Oct 2020'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:46:32

US3342281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:46:32

US3342281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:29:50
User entered 'Yes (Y)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:46:32

US3342281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:29:50
User entered '13:42'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:46:32

US3342281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '27 Oct 2020 13:42'	System	29 Oct 2020 14:46:32

US3342281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:46:32

US3342281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:29:50
User entered 'No (N)'	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:46:32

US3342281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:29:50
User entered empty.	Morgan Schulle (b) (4) (b) (4)	29 Oct 2020 14:46:32

US3342281

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 14:46:32

US3342281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:32:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 19:59:53

US3342281

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Oct 2020 19:59:53

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:45:05', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'f70eb3f0-f7e0-427e-9fe9-852a7ccf0548'	System	27 Oct 2020 19:45:26
User entered 'Yes (Y)'	System	27 Oct 2020 19:45:26

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:45:15', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'f70eb3f0-f7e0-427e-9fe9-852a7ccf0548'	System	27 Oct 2020 19:45:26
User entered '99.0'	System	27 Oct 2020 19:45:26

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:45:19', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'f70eb3f0-f7e0-427e-9fe9-852a7ccf0548'	System	27 Oct 2020 19:45:26
User entered 'No (N)'	System	27 Oct 2020 19:45:26

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:45:24', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'f70eb3f0-f7e0-427e-9fe9-852a7ccf0548' User entered '27 Oct 2020 14:45'	System	27 Oct 2020 19:45:26
	System	27 Oct 2020 19:45:26

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 14:17'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 16:47'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:48:41', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '898dcf72-a0b0-477c-94fa-dd4783e4ce5a' User entered 'Yes (Y)'	System	28 Oct 2020 05:49:46
	System	28 Oct 2020 05:49:46

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:49:20', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '898dcf72-a0b0-477c-94fa-dd4783e4ce5a' User entered '95.0'	System	28 Oct 2020 05:49:46

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:49:30', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '898dcf72-a0b0-477c-94fa-dd4783e4ce5a' User entered 'Yes (Y)'	System	28 Oct 2020 05:49:46
	System	28 Oct 2020 05:49:46

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:49:40', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '898dcf72-a0b0-477c-94fa-dd4783e4ce5a' User entered '0'	System	28 Oct 2020 05:49:46

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication has been documented on concomitant medication list ' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 21:04:33
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:49:40', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '898dcf72-a0b0-477c-94fa-dd4783e4ce5a' User entered '1'	System	28 Oct 2020 05:49:46
	System	28 Oct 2020 05:49:46
	System	28 Oct 2020 05:49:46

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:49:44', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '898dcf72-a0b0-477c-94fa-dd4783e4ce5a' User entered '28 Oct 2020 00:49'	System	28 Oct 2020 05:49:46
	System	28 Oct 2020 05:49:46

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 17:42'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 2'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T16:59:22', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '263d4f6e-6770-47d0-9eb2-8f63ed53fe74'	System	28 Oct 2020 22:00:35
User entered 'Yes (Y)'	System	28 Oct 2020 22:00:35

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T16:59:37', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '263d4f6e-6770-47d0-9eb2-8f63ed53fe74' User entered '97.0'	System	28 Oct 2020 22:00:35

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:00:14', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '263d4f6e-6770-47d0-9eb2-8f63ed53fe74'	System	28 Oct 2020 22:00:35
User entered 'Yes (Y)'	System	28 Oct 2020 22:00:35

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:00:16', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '263d4f6e-6770-47d0-9eb2-8f63ed53fe74' User entered '0'	System	28 Oct 2020 22:00:35

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication has been documented on concomitant medication list ' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 21:04:51
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:00:16', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '263d4f6e-6770-47d0-9eb2-8f63ed53fe74' User entered '1'	System	28 Oct 2020 22:00:35
	System	28 Oct 2020 22:00:35
	System	28 Oct 2020 22:00:35

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:00:29', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '263d4f6e-6770-47d0-9eb2-8f63ed53fe74' User entered '28 Oct 2020 17:00'	System	28 Oct 2020 22:00:35
	System	28 Oct 2020 22:00:35

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 3'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:27:03', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '3d5113a8-e8be-4aec-8827-f8ddf7bad076'	System	29 Oct 2020 21:27:21
User entered 'Yes (Y)'	System	29 Oct 2020 21:27:21

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:27:08', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '3d5113a8-e8be-4aec-8827-f8ddf7bad076'	System	29 Oct 2020 21:27:21
User entered '97.6'	System	29 Oct 2020 21:27:21

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:27:11', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '3d5113a8-e8be-4aec-8827-f8ddf7bad076'	System	29 Oct 2020 21:27:21
User entered 'No (N)'	System	29 Oct 2020 21:27:21

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:27:15', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '3d5113a8-e8be-4aec-8827-f8ddf7bad076'	System	29 Oct 2020 21:27:21
User entered '29 Oct 2020 16:27'	System	29 Oct 2020 21:27:21

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 4'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:22:28', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '48ee5f4b-c436-441d-bb8b-2f0a2421c46e' User entered 'Yes (Y)'	System	31 Oct 2020 14:22:55
	System	31 Oct 2020 14:22:55

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:22:35', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '48ee5f4b-c436-441d-bb8b-2f0a2421c46e' User entered '97.0'	System	31 Oct 2020 14:22:55
	System	31 Oct 2020 14:22:55

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:22:41', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '48ee5f4b-c436-441d-bb8b-2f0a2421c46e' User entered 'Yes (Y)'	System	31 Oct 2020 14:22:55
	System	31 Oct 2020 14:22:55

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:22:48', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '48ee5f4b-c436-441d-bb8b-2f0a2421c46e' User entered '0'	System	31 Oct 2020 14:22:55

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Medication has been documented on concomitant medication list ' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 21:05:07
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:22:48', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '48ee5f4b-c436-441d-bb8b-2f0a2421c46e' User entered '1'	System	31 Oct 2020 14:22:55
	System	31 Oct 2020 14:22:55
	System	31 Oct 2020 14:22:55

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:22:52', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '48ee5f4b-c436-441d-bb8b-2f0a2421c46e' User entered '31 Oct 2020 09:22'	System	31 Oct 2020 14:22:55
	System	31 Oct 2020 14:22:55

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 5'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:19:52', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '2e7f59ef-7647-48fd-bb7b-c142808182f6'	System	01 Nov 2020 06:20:13
User entered 'Yes (Y)'	System	01 Nov 2020 06:20:13

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:00', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '2e7f59ef-7647-48fd-bb7b-c142808182f6'	System	01 Nov 2020 06:20:13
User entered '98.0'	System	01 Nov 2020 06:20:13

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:06', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '2e7f59ef-7647-48fd-bb7b-c142808182f6'	System	01 Nov 2020 06:20:13
User entered 'No (N)'	System	01 Nov 2020 06:20:13

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:08', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '2e7f59ef-7647-48fd-bb7b-c142808182f6'	System	01 Nov 2020 06:20:13
User entered '01 Nov 2020 01:20'	System	01 Nov 2020 06:20:13

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 6'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:08', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'af52f941-334f-4a22-b79a-f68f8f41a3ff'	System	02 Nov 2020 04:11:30
User entered 'Yes (Y)'	System	02 Nov 2020 04:11:30

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:18', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'af52f941-334f-4a22-b79a-f68f8f41a3ff'	System	02 Nov 2020 04:11:30
User entered '98.0'	System	02 Nov 2020 04:11:30

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:24', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'af52f941-334f-4a22-b79a-f68f8f41a3ff'	System	02 Nov 2020 04:11:30
User entered 'No (N)'	System	02 Nov 2020 04:11:30

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:26', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'af52f941-334f-4a22-b79a-f68f8f41a3ff'	System	02 Nov 2020 04:11:30
User entered '01 Nov 2020 22:11'	System	02 Nov 2020 04:11:30

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 7'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T17:59:18', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '4b1cd58f-9fe6-4063-8586-437e2f6f1879'	System	02 Nov 2020 23:59:38
User entered 'Yes (Y)'	System	02 Nov 2020 23:59:38

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T17:59:24', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '4b1cd58f-9fe6-4063-8586-437e2f6f1879'	System	02 Nov 2020 23:59:38
User entered '98.2'	System	02 Nov 2020 23:59:38

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T17:59:33', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '4b1cd58f-9fe6-4063-8586-437e2f6f1879'	System	02 Nov 2020 23:59:38
User entered 'No (N)'	System	02 Nov 2020 23:59:38

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T17:59:36', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '4b1cd58f-9fe6-4063-8586-437e2f6f1879'	System	02 Nov 2020 23:59:38
User entered '02 Nov 2020 17:59'	System	02 Nov 2020 23:59:38

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:45:34', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5916a19f-a05a-4257-8271-088e394ce00d'	System	27 Oct 2020 19:46:01
User entered 'None (1)'	System	27 Oct 2020 19:46:01

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:45:39', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5916a19f-a05a-4257-8271-088e394ce00d'	System	27 Oct 2020 19:46:01
User entered 'No (N)'	System	27 Oct 2020 19:46:01

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:45:42', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5916a19f-a05a-4257-8271-088e394ce00d'	System	27 Oct 2020 19:46:01
User entered 'No (N)'	System	27 Oct 2020 19:46:01

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:45:52', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5916a19f-a05a-4257-8271-088e394ce00d' User entered 'None (1)'	System	27 Oct 2020 19:46:01
	System	27 Oct 2020 19:46:01

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:45:56', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '5916a19f-a05a-4257-8271-088e394ce00d' User entered '27 Oct 2020 14:45'	System	27 Oct 2020 19:46:01
	System	27 Oct 2020 19:46:01

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 14:17'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 16:47'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:49:53', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7e15a52-5c4c-467c-ac13-16f910f3a086'	System	28 Oct 2020 05:50:52
User entered 'Does not interfere with activity (2)'	System	28 Oct 2020 05:50:52

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:50:39', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7e15a52-5c4c-467c-ac13-16f910f3a086'	System	28 Oct 2020 05:50:52
User entered 'No (N)'	System	28 Oct 2020 05:50:52

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:50:43', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7e15a52-5c4c-467c-ac13-16f910f3a086'	System	28 Oct 2020 05:50:52
User entered 'No (N)'	System	28 Oct 2020 05:50:52

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:50:46', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7e15a52-5c4c-467c-ac13-16f910f3a086'	System	28 Oct 2020 05:50:52
User entered 'None (1)'	System	28 Oct 2020 05:50:52

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:50:49', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'e7e15a52-5c4c-467c-ac13-16f910f3a086'	System	28 Oct 2020 05:50:52
User entered '28 Oct 2020 00:50'	System	28 Oct 2020 05:50:52

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 17:42'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 2'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:00:39', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c292f560-dc44-41c3-ba59-3f884455b516'	System	28 Oct 2020 22:01:00
User entered 'Does not interfere with activity (2)'	System	28 Oct 2020 22:01:00

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:00:42', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c292f560-dc44-41c3-ba59-3f884455b516'	System	28 Oct 2020 22:01:00
User entered 'No (N)'	System	28 Oct 2020 22:01:00

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:00:45', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c292f560-dc44-41c3-ba59-3f884455b516'	System	28 Oct 2020 22:01:00
User entered 'No (N)'	System	28 Oct 2020 22:01:00

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:00:54', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c292f560-dc44-41c3-ba59-3f884455b516' User entered 'None (1)'	System	28 Oct 2020 22:01:00
	System	28 Oct 2020 22:01:00

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:00:57', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'c292f560-dc44-41c3-ba59-3f884455b516'	System	28 Oct 2020 22:01:00
User entered '28 Oct 2020 17:00'	System	28 Oct 2020 22:01:00

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 3'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:27:22', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '89bbc20b-aad0-4bde-93f4-3ac75e450575'	System	29 Oct 2020 21:28:07
User entered 'Does not interfere with activity (2)'	System	29 Oct 2020 21:28:07

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:27:52', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '89bbc20b-aad0-4bde-93f4-3ac75e450575'	System	29 Oct 2020 21:28:07
User entered 'No (N)'	System	29 Oct 2020 21:28:07

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:27:56', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '89bbc20b-aad0-4bde-93f4-3ac75e450575'	System	29 Oct 2020 21:28:07
User entered 'No (N)'	System	29 Oct 2020 21:28:07

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:27:58', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '89bbc20b-aad0-4bde-93f4-3ac75e450575'	System	29 Oct 2020 21:28:07
User entered 'None (1)'	System	29 Oct 2020 21:28:07

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:28:01', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '89bbc20b-aad0-4bde-93f4-3ac75e450575' User entered '29 Oct 2020 16:28'	System	29 Oct 2020 21:28:07
	System	29 Oct 2020 21:28:07

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 4'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:23:03', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '947048bc-d555-4477-a740-89c4d09c4ab9'	System	31 Oct 2020 14:23:52
User entered 'Does not interfere with activity (2)'	System	31 Oct 2020 14:23:52

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:23:07', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '947048bc-d555-4477-a740-89c4d09c4ab9'	System	31 Oct 2020 14:23:52
User entered 'No (N)'	System	31 Oct 2020 14:23:52

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:23:44', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '947048bc-d555-4477-a740-89c4d09c4ab9'	System	31 Oct 2020 14:23:52
User entered 'No (N)'	System	31 Oct 2020 14:23:52

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:23:47', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '947048bc-d555-4477-a740-89c4d09c4ab9' User entered 'None (1)'	System	31 Oct 2020 14:23:52
	System	31 Oct 2020 14:23:52

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:23:50', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '947048bc-d555-4477-a740-89c4d09c4ab9' User entered '31 Oct 2020 09:23'	System	31 Oct 2020 14:23:52
	System	31 Oct 2020 14:23:52

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 5'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:19', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '54ae2379-48e9-4831-9df6-7642ea7443d2'	System	01 Nov 2020 06:20:37
User entered 'None (1)'	System	01 Nov 2020 06:20:37

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:22', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '54ae2379-48e9-4831-9df6-7642ea7443d2'	System	01 Nov 2020 06:20:37
User entered 'No (N)'	System	01 Nov 2020 06:20:37

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:26', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '54ae2379-48e9-4831-9df6-7642ea7443d2'	System	01 Nov 2020 06:20:37
User entered 'No (N)'	System	01 Nov 2020 06:20:37

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:28', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '54ae2379-48e9-4831-9df6-7642ea7443d2'	System	01 Nov 2020 06:20:37
User entered 'None (1)'	System	01 Nov 2020 06:20:37

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:31', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '54ae2379-48e9-4831-9df6-7642ea7443d2'	System	01 Nov 2020 06:20:37
User entered '01 Nov 2020 01:20'	System	01 Nov 2020 06:20:37

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 6'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:31', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '796f879d-fcba-47c1-bd0a-ac5f5c06843e'	System	02 Nov 2020 04:11:47
User entered 'None (1)'	System	02 Nov 2020 04:11:47

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:34', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '796f879d-fcba-47c1-bd0a-ac5f5c06843e'	System	02 Nov 2020 04:11:47
User entered 'No (N)'	System	02 Nov 2020 04:11:47

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:37', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '796f879d-fcba-47c1-bd0a-ac5f5c06843e'	System	02 Nov 2020 04:11:47
User entered 'No (N)'	System	02 Nov 2020 04:11:47

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:41', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '796f879d-fcba-47c1-bd0a-ac5f5c06843e' User entered 'None (1)'	System	02 Nov 2020 04:11:47

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:44', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '796f879d-fcba-47c1-bd0a-ac5f5c06843e'	System	02 Nov 2020 04:11:47
User entered '01 Nov 2020 22:11'	System	02 Nov 2020 04:11:47

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 7'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T17:59:42', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ad4dd34a-d65f-46ca-9c85-d8ec984e7500'	System	02 Nov 2020 23:59:58
User entered 'None (1)'	System	02 Nov 2020 23:59:58

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T17:59:46', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ad4dd34a-d65f-46ca-9c85-d8ec984e7500'	System	02 Nov 2020 23:59:58
User entered 'No (N)'	System	02 Nov 2020 23:59:58

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T17:59:50', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ad4dd34a-d65f-46ca-9c85-d8ec984e7500'	System	02 Nov 2020 23:59:58
User entered 'No (N)'	System	02 Nov 2020 23:59:58

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T17:59:54', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ad4dd34a-d65f-46ca-9c85-d8ec984e7500'	System	02 Nov 2020 23:59:58
User entered 'None (1)'	System	02 Nov 2020 23:59:58

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T17:59:56', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ad4dd34a-d65f-46ca-9c85-d8ec984e7500'	System	02 Nov 2020 23:59:58
User entered '02 Nov 2020 17:59'	System	02 Nov 2020 23:59:58

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:46:33', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '8cd5352a-a9fd-42cb-8e4d-e070e7d533d9'	System	27 Oct 2020 19:47:12
User entered 'None (0)'	System	27 Oct 2020 19:47:12

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:46:50', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '8cd5352a-a9fd-42cb-8e4d-e070e7d533d9' User entered 'None (0)'	System	27 Oct 2020 19:47:12

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:46:53', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '8cd5352a-a9fd-42cb-8e4d-e070e7d533d9'	System	27 Oct 2020 19:47:12
User entered 'None (0)'	System	27 Oct 2020 19:47:12

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:46:56', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '8cd5352a-a9fd-42cb-8e4d-e070e7d533d9'	System	27 Oct 2020 19:47:12
User entered 'None (0)'	System	27 Oct 2020 19:47:12

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:46:59', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '8cd5352a-a9fd-42cb-8e4d-e070e7d533d9'	System	27 Oct 2020 19:47:12
User entered 'None (0)'	System	27 Oct 2020 19:47:12

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:47:02', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '8cd5352a-a9fd-42cb-8e4d-e070e7d533d9'	System	27 Oct 2020 19:47:12
User entered 'None (0)'	System	27 Oct 2020 19:47:12

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:47:06', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '8cd5352a-a9fd-42cb-8e4d-e070e7d533d9'	System	27 Oct 2020 19:47:12
User entered 'No (N)'	System	27 Oct 2020 19:47:12

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-27T14:47:09', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '8cd5352a-a9fd-42cb-8e4d-e070e7d533d9' User entered '27 Oct 2020 14:47'	System	27 Oct 2020 19:47:12

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 14:17'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 16:47'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:50:58', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11e190e3-d6d5-4a44-a3dd-9dedfc5b7708'	System	28 Oct 2020 05:51:21
User entered 'No interference with activity (1)'	System	28 Oct 2020 05:51:21

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:51:02', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11e190e3-d6d5-4a44-a3dd-9dedfc5b7708'	System	28 Oct 2020 05:51:21
User entered 'None (0)'	System	28 Oct 2020 05:51:21

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:51:05', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11e190e3-d6d5-4a44-a3dd-9dedfc5b7708' User entered 'None (0)'	System	28 Oct 2020 05:51:21
	System	28 Oct 2020 05:51:21

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:51:08', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11e190e3-d6d5-4a44-a3dd-9dedfc5b7708' User entered 'None (0)'	System	28 Oct 2020 05:51:21
	System	28 Oct 2020 05:51:21

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:51:11', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11e190e3-d6d5-4a44-a3dd-9dedfc5b7708'	System	28 Oct 2020 05:51:21
User entered 'None (0)'	System	28 Oct 2020 05:51:21

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:51:13', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11e190e3-d6d5-4a44-a3dd-9dedfc5b7708'	System	28 Oct 2020 05:51:21
User entered 'None (0)'	System	28 Oct 2020 05:51:21

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:51:17', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11e190e3-d6d5-4a44-a3dd-9dedfc5b7708'	System	28 Oct 2020 05:51:21
User entered 'No (N)'	System	28 Oct 2020 05:51:21

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T00:51:20', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '11e190e3-d6d5-4a44-a3dd-9dedfc5b7708' User entered '28 Oct 2020 00:51'	System	28 Oct 2020 05:51:21
	System	28 Oct 2020 05:51:21

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 17:42'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 2'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:01:08', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9c4ed62b-23ac-44ca-b85b-1ea8f8ff6109'	System	28 Oct 2020 22:01:41
User entered 'None (0)'	System	28 Oct 2020 22:01:41

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:01:11', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9c4ed62b-23ac-44ca-b85b-1ea8f8ff6109'	System	28 Oct 2020 22:01:41
User entered 'None (0)'	System	28 Oct 2020 22:01:41

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:01:16', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9c4ed62b-23ac-44ca-b85b-1ea8f8ff6109'	System	28 Oct 2020 22:01:41
User entered 'No interference with activity (1)'	System	28 Oct 2020 22:01:41

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:01:19', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9c4ed62b-23ac-44ca-b85b-1ea8f8ff6109'	System	28 Oct 2020 22:01:41
User entered 'None (0)'	System	28 Oct 2020 22:01:41

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:01:23', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9c4ed62b-23ac-44ca-b85b-1ea8f8ff6109'	System	28 Oct 2020 22:01:41
User entered 'None (0)'	System	28 Oct 2020 22:01:41

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:01:25', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9c4ed62b-23ac-44ca-b85b-1ea8f8ff6109'	System	28 Oct 2020 22:01:41
User entered 'None (0)'	System	28 Oct 2020 22:01:41

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:01:30', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9c4ed62b-23ac-44ca-b85b-1ea8f8ff6109'	System	28 Oct 2020 22:01:41
User entered 'No (N)'	System	28 Oct 2020 22:01:41

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-28T17:01:32', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '9c4ed62b-23ac-44ca-b85b-1ea8f8ff6109' User entered '28 Oct 2020 17:01'	System	28 Oct 2020 22:01:41
	System	28 Oct 2020 22:01:41

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 3'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:28:06', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '75a5d77d-ae77-4517-af9c-6bce9b8c33ed'	System	29 Oct 2020 21:28:58
User entered 'No interference with activity (1)'	System	29 Oct 2020 21:28:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:28:15', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '75a5d77d-ae77-4517-af9c-6bce9b8c33ed' User entered 'None (0)'	System	29 Oct 2020 21:28:58
	System	29 Oct 2020 21:28:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:28:25', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '75a5d77d-ae77-4517-af9c-6bce9b8c33ed'	System	29 Oct 2020 21:28:58
User entered 'No interference with activity (1)'	System	29 Oct 2020 21:28:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:28:29', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '75a5d77d-ae77-4517-af9c-6bce9b8c33ed'	System	29 Oct 2020 21:28:58
User entered 'No interference with activity (1)'	System	29 Oct 2020 21:28:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:28:46', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '75a5d77d-ae77-4517-af9c-6bce9b8c33ed'	System	29 Oct 2020 21:28:58
User entered 'None (0)'	System	29 Oct 2020 21:28:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:28:49', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '75a5d77d-ae77-4517-af9c-6bce9b8c33ed'	System	29 Oct 2020 21:28:58
User entered 'None (0)'	System	29 Oct 2020 21:28:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:28:54', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '75a5d77d-ae77-4517-af9c-6bce9b8c33ed'	System	29 Oct 2020 21:28:58
User entered 'No (N)'	System	29 Oct 2020 21:28:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-29T16:28:57', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '75a5d77d-ae77-4517-af9c-6bce9b8c33ed' User entered '29 Oct 2020 16:28'	System	29 Oct 2020 21:28:58
	System	29 Oct 2020 21:28:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 4'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:23:58', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fef6c844-8303-4480-a0d0-e0ec3337cca9'	System	31 Oct 2020 14:24:45
User entered 'No interference with activity (1)'	System	31 Oct 2020 14:24:45

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:24:02', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fef6c844-8303-4480-a0d0-e0ec3337cca9' User entered 'None (0)'	System	31 Oct 2020 14:24:45
	System	31 Oct 2020 14:24:45

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:24:12', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fef6c844-8303-4480-a0d0-e0ec3337cca9'	System	31 Oct 2020 14:24:45
User entered 'Some interference with activity (2)'	System	31 Oct 2020 14:24:45

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:24:16', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fef6c844-8303-4480-a0d0-e0ec3337cca9'	System	31 Oct 2020 14:24:45
User entered 'No interference with activity (1)'	System	31 Oct 2020 14:24:45

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:24:20', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fef6c844-8303-4480-a0d0-e0ec3337cca9'	System	31 Oct 2020 14:24:45
User entered 'None (0)'	System	31 Oct 2020 14:24:45

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:24:24', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fef6c844-8303-4480-a0d0-e0ec3337cca9'	System	31 Oct 2020 14:24:45
User entered 'None (0)'	System	31 Oct 2020 14:24:45

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:24:37', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fef6c844-8303-4480-a0d0-e0ec3337cca9'	System	31 Oct 2020 14:24:45
User entered 'Yes (Y)'	System	31 Oct 2020 14:24:45

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-10-31T09:24:43', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'fef6c844-8303-4480-a0d0-e0ec3337cca9' User entered '31 Oct 2020 09:24'	System	31 Oct 2020 14:24:45
	System	31 Oct 2020 14:24:45

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 5'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:45', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '659916f2-be17-4465-a086-47f5f3d956db'	System	01 Nov 2020 06:21:10
User entered 'None (0)'	System	01 Nov 2020 06:21:10

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:49', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '659916f2-be17-4465-a086-47f5f3d956db' User entered 'None (0)'	System	01 Nov 2020 06:21:10

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:51', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '659916f2-be17-4465-a086-47f5f3d956db' User entered 'None (0)'	System	01 Nov 2020 06:21:10
	System	01 Nov 2020 06:21:10

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:54', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '659916f2-be17-4465-a086-47f5f3d956db'	System	01 Nov 2020 06:21:10
User entered 'None (0)'	System	01 Nov 2020 06:21:10

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:57', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '659916f2-be17-4465-a086-47f5f3d956db'	System	01 Nov 2020 06:21:10
User entered 'None (0)'	System	01 Nov 2020 06:21:10

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:20:59', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '659916f2-be17-4465-a086-47f5f3d956db' User entered 'None (0)'	System	01 Nov 2020 06:21:10

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:21:04', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '659916f2-be17-4465-a086-47f5f3d956db'	System	01 Nov 2020 06:21:10
User entered 'No (N)'	System	01 Nov 2020 06:21:10

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T01:21:06', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '659916f2-be17-4465-a086-47f5f3d956db' User entered '01 Nov 2020 01:21'	System	01 Nov 2020 06:21:10

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 6'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:56', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '14873102-1548-4a68-9096-f7bba9809312'	System	02 Nov 2020 04:12:16
User entered 'None (0)'	System	02 Nov 2020 04:12:16

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:11:59', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '14873102-1548-4a68-9096-f7bba9809312'	System	02 Nov 2020 04:12:16
User entered 'None (0)'	System	02 Nov 2020 04:12:16

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:12:02', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '14873102-1548-4a68-9096-f7bba9809312'	System	02 Nov 2020 04:12:16
User entered 'None (0)'	System	02 Nov 2020 04:12:16

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:12:04', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '14873102-1548-4a68-9096-f7bba9809312'	System	02 Nov 2020 04:12:16
User entered 'None (0)'	System	02 Nov 2020 04:12:16

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:12:06', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '14873102-1548-4a68-9096-f7bba9809312'	System	02 Nov 2020 04:12:16
User entered 'None (0)'	System	02 Nov 2020 04:12:16

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:12:08', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '14873102-1548-4a68-9096-f7bba9809312'	System	02 Nov 2020 04:12:16
User entered 'None (0)'	System	02 Nov 2020 04:12:16

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:12:11', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '14873102-1548-4a68-9096-f7bba9809312'	System	02 Nov 2020 04:12:16
User entered 'No (N)'	System	02 Nov 2020 04:12:16

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-01T22:12:14', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '14873102-1548-4a68-9096-f7bba9809312'	System	02 Nov 2020 04:12:16
User entered '01 Nov 2020 22:12'	System	02 Nov 2020 04:12:16

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Oct 2020 19:29:29
User entered 'Day 7'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T18:00:07', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ef82121e-22fb-4deb-989d-f32959604a1e'	System	03 Nov 2020 00:00:58
User entered 'None (0)'	System	03 Nov 2020 00:00:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T18:00:13', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ef82121e-22fb-4deb-989d-f32959604a1e'	System	03 Nov 2020 00:00:58
User entered 'None (0)'	System	03 Nov 2020 00:00:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T18:00:17', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ef82121e-22fb-4deb-989d-f32959604a1e'	System	03 Nov 2020 00:00:58
User entered 'None (0)'	System	03 Nov 2020 00:00:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T18:00:27', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ef82121e-22fb-4deb-989d-f32959604a1e'	System	03 Nov 2020 00:00:58
User entered 'None (0)'	System	03 Nov 2020 00:00:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T18:00:37', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ef82121e-22fb-4deb-989d-f32959604a1e'	System	03 Nov 2020 00:00:58
User entered 'None (0)'	System	03 Nov 2020 00:00:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T18:00:42', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ef82121e-22fb-4deb-989d-f32959604a1e'	System	03 Nov 2020 00:00:58
User entered 'None (0)'	System	03 Nov 2020 00:00:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

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 (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T18:00:48', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ef82121e-22fb-4deb-989d-f32959604a1e'	System	03 Nov 2020 00:00:58
User entered 'No (N)'	System	03 Nov 2020 00:00:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-02T18:00:53', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: 'ef82121e-22fb-4deb-989d-f32959604a1e'	System	03 Nov 2020 00:00:58
User entered '02 Nov 2020 18:00'	System	03 Nov 2020 00:00:58

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 19:29:29

US3342281

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:57:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 19:29:29

US3342281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:01:21

US3342281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 20:01:21

US3342281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Nov 2020 20:01:21

US3342281

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:01:21

US3342281

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:01:25

US3342281

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 20:01:25

US3342281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 16:38:30

US3342281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 16:38:30

US3342281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 16:38:30

US3342281

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 16:38:30

US3342281

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 16:38:37

US3342281

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 16:38:37

US3342281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 16:34:32

US3342281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 16:34:32

US3342281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 16:34:32

US3342281

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:57:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 16:34:32

US3342281

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 16:34:38

US3342281

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 16:34:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:13

US3342281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:13

US3342281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:13

US3342281

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:57:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	23 Nov 2020 20:26:13

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '10:25'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '23 Nov 2020 10:25'	System	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '72'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered '16'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '80'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:57:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Nov 2020 20:26:38

US3342281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:46

US3342281

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:57:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:46

US3342281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:26:53

US3342281

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:57:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 20:26:53

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-23T10:49:57', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6d086800-4cd2-496e-9465-c373ff137e71' User entered 'No (N)'	System	23 Nov 2020 16:50:12
	System	23 Nov 2020 16:50:12

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-23T10:50:04', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6d086800-4cd2-496e-9465-c373ff137e71'	System	23 Nov 2020 16:50:12
User entered 'No (N)'	System	23 Nov 2020 16:50:12

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5795B5AF-C52A-4D26-A42F-82E8388806E8)', Time: '2020-11-23T10:50:10', User OID: 'PatientReportedOutcome (US3342281)', ODM File OID: '6d086800-4cd2-496e-9465-c373ff137e71'	System	23 Nov 2020 16:50:12
User entered '23 Nov 2020 10:50:10'	System	23 Nov 2020 16:50:12

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 10:35:26

US3342281

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:57:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:35:26
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 10:35:26

US3342281

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:57:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:20:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 20:02:05

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Papulosquamous conditions, PT: Pityriasis rosea, LLT: Pityriasis rosea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:04:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:04:28
Data point term sent to Coder	System	03 Nov 2020 20:03:06
Coding entries removed.	(b) (4), (b) (6)	03 Nov 2020 20:03:05
User entered 'Pityriasis Rosea' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:03:05
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Contact dermatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 20:05:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 20:05:24
Data point term sent to Coder	System	27 Oct 2020 20:04:13
User entered 'Contact Dermatitis'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please update date to reflect (dd MMM yyyy) format. Thank you' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:44:30
Query 'Per CDM: Please update date to reflect (dd MMM yyyy) format. Thank you' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4)	12 Nov 2020 20:13:13
DataPoint Un-verified.	(b) (4)	
	Eileen Euperio (b) (4)	12 Nov 2020 20:13:06
	(b) (4)	
User entered '08 Oct 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	12 Nov 2020 20:13:06
	(b) (4)	
User opened query 'Per CDM: Please update date to reflect (dd MMM yyyy) format. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 18:43:35
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '8 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'None (NONE)'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '1'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:57:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 20:03:42

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:10
User entered 'USA-US203-2020-mRNA-1273-P301000004'	System	04 Nov 2020 15:38:59
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 15:38:59

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Concussion, LLT: Concussion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 20:07:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 20:07:24
Data point term sent to Coder	System	27 Oct 2020 20:06:17
User entered 'Concussion'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User closed query 'According to source subject went to the hospital for this. Should this be answered "yes"? Please update or clarify.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 05:25:32
Query 'According to source subject went to the hospital for this. Should this be answered "yes"? Please update or clarify.' answered with 'updated' (Site from CRA).	Eileen Euperio (b) (4)	17 Nov 2020 23:43:32
DataPoint Un-verified.	(b) (4)	17 Nov 2020 23:43:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	17 Nov 2020 23:43:28
User opened query 'According to source subject went to the hospital for this. Should this be answered "yes"? Please update or clarify.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:29:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 20:10:47
User entered '04:30' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 20:10:47
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 20:05:27
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 04:30'	System	27 Oct 2020 20:10:47
User entered empty.	System	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Eileen Euperio (b) (4)	23 Nov 2020 20:27:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	23 Nov 2020 20:27:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Eileen Euperio (b) (4)	23 Nov 2020 20:27:32
	(b) (4)	
User entered '20 Nov 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	23 Nov 2020 20:27:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Nov 2020 20:28:26
DataPoint Un-verified.	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:28:26
User entered '10:00' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	23 Nov 2020 20:28:26
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Nov 2020 20:27:32
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 10:00'	System	23 Nov 2020 20:28:26
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:06:27
User entered empty.	System	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		03 Nov 2020 18:21:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 18:21:32
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	03 Nov 2020 18:21:19
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 14:26:28
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Hospital admission and discharge date have been provided' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 18:22:13
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		03 Nov 2020 18:21:19
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		03 Nov 2020 18:21:19
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 Nov 2020 18:21:19
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 18:21:19
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	03 Nov 2020 18:21:08
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 18:21:08
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '30 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 18:21:08
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'None (NONE)'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 18:21:08
User entered '1'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 18:21:08
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:28:09
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'UPDATED OUTCOME' (Site from Safety).	Eileen Euperio (b) (4)	23 Nov 2020 20:28:41
DataPoint Un-verified.	(b) (4)	23 Nov 2020 20:27:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	23 Nov 2020 20:27:32
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:08:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide details on how the subject obtained the head trauma. ' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 14:56:55
Query 'PV Query: Please provide details on how the subject obtained the head trauma. ' answered with 'UPDATED, SUBJECT WAS ROBBED AND SUSTAINED CONCUSSION DUE TO PHYSICAL BATTERY' (Site from Safety).	Eileen Euperio (b) (4)	18 Nov 2020 14:40:36
DataPoint Un-verified.	Eileen Euperio (b) (4)	18 Nov 2020 14:40:07
User entered 'PATIENT REPORTED A HEAD TRAUMA AS A RESULT OF PHYSICAL BATTERY ON 27OCT2020 AT 04:30. BY 29OCT2020 THE PATIENT WAS IN A LOT OF PAIN AND DECIDED TO GO TO THE HOSPITAL. HE WAS ADMITTED FOR ONE NIGHT. TWO SCANS WERE PREFORMED. PATIENT REPORTED BLEEDING ON THE LEFT SIDE OF HIS BRAIN.' reason for change: Data Entry Error	Eileen Euperio (b) (4)	18 Nov 2020 14:40:07
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)	12 Nov 2020 21:07:16
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:07:09
User opened query 'PV Query: Please provide details on how the subject obtained the head trauma. ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 21:05:45
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Patient reported a head trauma on 27Oct2020 at 04:30. By 29Oct2020 the patient was in a lot of pain and decided to go to the hospital. He was admitted for one night. Two scans were preformed. Patient reported bleeding on the left side of his brain.' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 18:21:08
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 18:21:32
User entered '0'	System	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:57:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 23:43:28
User entered '0'	System	27 Oct 2020 20:05:27

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Lip injury, LLT: Lip laceration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 22:29:31
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 22:29:31
Data point term sent to Coder	System	27 Oct 2020 20:13:31
User entered 'Laceration left upper lip'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '04:30'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020 04:30'	System	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:44:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '29 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:44:11
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '12:00' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:44:11
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Oct 2020 12:00'	System	03 Nov 2020 17:44:11
User entered empty.	System	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'None (NONE)'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '1'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 17:44:11
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:23:05
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 20:12:54

US3342281

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:57:19

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 20:12:54

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:57:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:27:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:53:32

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:56:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 15:56:51
Data point term sent to Coder	System	24 Sep 2020 15:55:42
User entered 'Loratadine'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Seasonal Allergies'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '10'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'as needed (PRN)'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'UN UNK 2015'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '0'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 15:54:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM HYDROXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:17:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:17:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM HYDROXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:17:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:17:39
Data point term sent to Coder	System	19 Oct 2020 19:47:27
User entered 'Magnesium hydroxide'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'nausea/vomiting'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '2400'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'as needed (PRN)'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '0'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '16 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 19:46:42

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:31:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:31:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
Data point term sent to Coder	System	10 Nov 2020 16:39:20
Coding entries removed.	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 16:39:07
User entered 'HYDROCORTISONE TOPICAL 1%' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 16:39:07
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, WEAK (GROUP I), PRODUCT: HYDROCORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:08:22
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 17:08:22
Data point term sent to Coder	System	27 Oct 2020 20:02:09
User entered 'hydrocortisone topical'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Contact Dermatitis'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User closed query 'Per CDM: Per CCGs, only numerals should be present in dose per administration field. Please reconcile and consider adding to name of medication. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:47:41
Query 'Per CDM: Per CCGs, only numerals should be present in dose per administration field. Please reconcile and consider adding to name of medication. Thank you' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4)	10 Nov 2020 16:39:23
User entered '1' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 16:39:07
User opened query 'Per CDM: Per CCGs, only numerals should be present in dose per administration field. Please reconcile and consider adding to name of medication. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:28:41
User entered '1%'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Other (OTHER)'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'APPLICATION' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 16:39:07
User entered '1 Application'	(b) (4)	27 Oct 2020 20:01:43
	(b) (4), (b) (6)	

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User closed query 'Per CDM: Please update date to reflect (dd MMM yyyy) format. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:47:45
Query 'Per CDM: Please update date to reflect (dd MMM yyyy) format. Thank you' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 16:39:27
User entered '09 Oct 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4) (b) (4)	10 Nov 2020 16:39:17
User opened query 'Per CDM: Please update date to reflect (dd MMM yyyy) format. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:32:00
User entered '9 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '0'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '13 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 20:01:43

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 21:12:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	03 Nov 2020 21:12:25
Data point term sent to Coder	System	03 Nov 2020 21:11:31
User entered 'Acetaminophen'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 21:12:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Concussion: AE'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '1000'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '30 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:11:23

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:16:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:16:20
Data point term sent to Coder	System	03 Nov 2020 21:12:32
User entered 'Levetiracetam'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:26:02
User closed query 'Per CDM: Please confirm if this medication is taken prophylactically, as it is associated with an AE. Thank you' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:32:12
Query 'Per CDM: Please confirm if this medication is taken prophylactically, as it is associated with an AE. Thank you' answered with 'updated' (Site from DM).	Eileen Euperio (b) (4)	12 Nov 2020 20:12:49
DataPoint Un-verified.	(b) (4)	12 Nov 2020 20:12:44
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	12 Nov 2020 20:12:44
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User opened query 'Per CDM: Please confirm if this medication is taken prophylactically, as it is associated with an AE. Thank you' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 20:33:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Concussion: AE'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '500'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'twice daily (BID)'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '30 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 16:42:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '07 Nov 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 16:42:27
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 21:12:20

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:18:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:18:18
Data point term sent to Coder	System	03 Nov 2020 21:14:35
User entered 'Methocarbamol'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Concussion: AE'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '750'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '30 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 16:40:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '07 Nov 2020' reason for change: Data Entry Error	Eileen Euperio (b) (4)	10 Nov 2020 16:40:20
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:13:35

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 21:16:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	03 Nov 2020 21:16:28
Data point term sent to Coder	System	03 Nov 2020 21:15:36
User entered 'Acetaminophen'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Headache: AR after vaccine #2'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '1000'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'as needed (PRN)'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '27 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered '30 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:41:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:15:07

US3342281

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:57:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 21:15:07

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'USA-US203-2020-MRNA-1273-P301000004'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'Yes (Y)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'Yes (Y)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:57:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
User entered 'US'	System	04 Nov 2020 15:40:03

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 20:29:34
User entered '2'	System	18 Nov 2020 14:57:15
User entered '1'	System	04 Nov 2020 15:40:03

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'USA-US203-2020-MRNA-1273-P301000004'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'Yes (Y)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'Yes (Y)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:57:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
User entered 'US'	System	04 Nov 2020 15:40:03

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 20:29:34
User entered '2'	System	18 Nov 2020 14:57:15
User entered '1'	System	04 Nov 2020 15:40:03

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:57:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
User entered '04/Nov/2020 10:39'	System	04 Nov 2020 15:40:03

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:57:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:57:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
User entered 'I'	(b) (4), (b) (6)	04 Nov 2020 15:40:03

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'USA-US203-2020-MRNA-1273-P301000004'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'Yes (Y)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'Yes (Y)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:57:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
User entered 'US'	System	04 Nov 2020 15:40:03

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 20:29:34
User entered '2'	System	18 Nov 2020 14:57:15
User entered '1'	System	04 Nov 2020 15:40:03

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:57:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '18/Nov/2020 09:57'	System	18 Nov 2020 14:57:15

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:57:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 20:29:15
User entered 'I'	(b) (4), (b) (6)	18 Nov 2020 14:57:15

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'USA-US203-2020-MRNA-1273-P301000004'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'Yes (Y)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'Yes (Y)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 15:39:45
User entered 'No (N)'	System	04 Nov 2020 15:38:59

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 14:57:05
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:21:13
User entered 'US'	System	04 Nov 2020 15:40:03

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 10:57:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 20:29:34
User entered '2'	System	18 Nov 2020 14:57:15
User entered '1'	System	04 Nov 2020 15:40:03

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:57:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 15:29'	System	24 Nov 2020 20:29:34

US3342281

Folder: SAE USA-US203-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:57:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 20:29:34