

US3282113 (Prod: Foothill Family Clinic-South Clinic)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:54:31

All time stamps listed in this document are displayed in GMT

US3282113

Form: Participant Creation

Generated On: 26 Nov 2020 10:54:31

[Participant ID](#)

US3282113

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

US3282113

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:54:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:54:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN SEP 2018
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)	SEP 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

Condition	INTERMITTENT MIDSTERNAL CHEST PAIN, CARDIAC
Start date (dd MMM yyyy)	UN UNK 2010
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)	02 NOV 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	NOV 2020
Stop Year (derived)	2020

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	15:12 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 15:12
Height (<i>xxx.x</i>)	71.0 in
Weight (<i>xxx.x</i>)	214.6 lb
BMI (<i>xxx.x</i>)	29.99321 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)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

MICROBIOLOGY LAB WITH
ABOUT 65 OTHER STAFF
MEMBERS

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

What was the date of randomization? (dd MMM yyyy) 16 OCT 2020

What was the participant's randomization number? 191382

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Height	ND - Not Done
Weight	ND - Not Done
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)	16 OCT 2020
Time of assessment (00:00-23:59)	15:12 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 15:12
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Height	ND - Not Done
Weight	ND - Not Done
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)	16 OCT 2020
Time of assessment (00:00-23:59)	16:59 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 16:59
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 16 OCT 2020

What was the treatment time? (00:00-23:59) 16:20 (24 HR)

Treatment Date and Time (derived) 16 OCT 2020 16:20

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	16 OCT 2020
Collection time (<i>00:00-23:59</i>)	15:33 (24 HR)
Collection date and time (derived)	16 OCT 2020 15:33

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:31

Collection date (dd MMM yyyy)			16 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:30	16 OCT 2020 15:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

16 OCT 2020 17:04

PC Open Date & Time

16 OCT 2020 16:40

PC Close Date & Time

16 OCT 2020 19:10

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 16 OCT 2020 20:05

PC Close Date & Time 17 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

18 OCT 2020 01:41

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 19:32

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 OCT 2020 12:50

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 19:15

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

97.2 °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

21 OCT 2020 12:09

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 OCT 2020 17:04

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

16 OCT 2020 17:06

PC Open Date & Time

16 OCT 2020 16:40

PC Close Date & Time

16 OCT 2020 19:10

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 OCT 2020 20:05

PC Close Date & Time

17 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

18 OCT 2020 01:42

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

18 OCT 2020 19:33

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

19 OCT 2020 12:50

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

20 OCT 2020 19:15

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

21 OCT 2020 12:10

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

22 OCT 2020 17:04

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

No ☒

Yes ☐

PC Time stamp	16 OCT 2020 17:07
PC Open Date & Time	16 OCT 2020 16:40
PC Close Date & Time	16 OCT 2020 19:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

16 OCT 2020 20:05

PC Close Date & Time

17 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 01:43
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 19:34
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 12:51
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 19:16
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 12:11
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 17:05
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3282113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

Was Contact Attempted?

Yes ☒

No ☐

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

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

Was Contact Attempted?

Yes ☒

No ☐

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

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

Was Contact Attempted?

Yes ☒

No ☐

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

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3282113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	VISIT2

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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)	19 NOV 2020
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 11:08
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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)	19 NOV 2020
Time of assessment (00:00-23:59)	13:07 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 13:07
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3282113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 NOV 2020

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

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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)	19 NOV 2020
What was the treatment time? (00:00-23:59)	12:37 (24 HR)
Treatment Date and Time (derived)	19 NOV 2020 12:37
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

US3282113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	19 NOV 2020
Collection time (<i>00:00-23:59</i>)	11:40 (24 HR)
Collection date and time (derived)	19 NOV 2020 11:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:31

Collection date (<i>dd MMM yyyy</i>)			19 NOV 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:45	19 NOV 2020 11:45
Nasopharyngeal Swab 2	No		

US3282113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °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 19 NOV 2020 13:08

PC Open Date & Time 19 NOV 2020 12:57

PC Close Date & Time 19 NOV 2020 15:27

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	19 NOV 2020 16:29
PC Open Date & Time	19 NOV 2020 16:22
PC Close Date & Time	20 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 20 NOV 2020 12:00

PC Close Date & Time 21 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

97.4 °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

21 NOV 2020 18:03

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

97.9 °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

22 NOV 2020 12:14

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 NOV 2020 12:35

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 NOV 2020 21:59

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 25 NOV 2020 12:00

PC Close Date & Time 26 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 NOV 2020 13:10

PC Open Date & Time

19 NOV 2020 12:57

PC Close Date & Time

19 NOV 2020 15:27

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 NOV 2020 16:30

PC Open Date & Time

19 NOV 2020 16:22

PC Close Date & Time

20 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 NOV 2020 18:04

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 NOV 2020 12:15

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 NOV 2020 12:35

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

24 NOV 2020 21:59

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 13:10
PC Open Date & Time	19 NOV 2020 12:57
PC Close Date & Time	19 NOV 2020 15:27

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

No ☒

Yes ☐

PC Time stamp	19 NOV 2020 16:31
PC Open Date & Time	19 NOV 2020 16:22
PC Close Date & Time	20 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

		Yes <input type="checkbox"/>
<hr/>		
PC Time stamp		
<hr/>		
PC Open Date & Time		20 NOV 2020 12:00
<hr/>		
PC Close Date & Time		21 NOV 2020 11:59
<hr/>		

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	21 NOV 2020 18:05
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	22 NOV 2020 12:15
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	23 NOV 2020 12:36
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 ☒

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

Yes <input type="checkbox"/>	
PC Time stamp	24 NOV 2020 22:01
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

Yes ☐

PC Time stamp

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3282113

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

US3282113

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

27 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

07 JAN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

14 JAN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

18 FEB 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 159

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 173

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 208

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 236

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 <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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 369

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 628

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	01 SEP 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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="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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 2022 00:01
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Patient Cloud Close Date & Time	27 OCT 2022 23:59
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US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 747

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	20 NOV 2022 00:01
Patient Cloud Close Date & Time	24 NOV 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	27 NOV 2022 00:01
Patient Cloud Close Date & Time	01 DEC 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	04 DEC 2022 00:01
Patient Cloud Close Date & Time	08 DEC 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

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

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

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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	11 DEC 2022 00:01
Patient Cloud Close Date & Time	15 DEC 2022 23:59

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

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

18 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2022 23:59

US3282113

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:54:31

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"/>

US3282113

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:54:31

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3282113

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:54:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

AEID	USA-US201-2020-MRNA-1273-P30 1000001
Adverse event	CORONARY ARTERY DISEASE
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)	23 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 type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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)	23 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	25 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

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	True
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	

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

SUBJECT CONTACTED SITE
STAFF TO INFORM OF RECENT
HOSPITALIZATION. THE
SUBJECT EXPERIENCED CHEST
PAIN ON 23OCT2020. THE
SUBJECT PRESENTED TO
HOSPITAL WHERE STRESS TEST
IDENTIFIED BLOCKED
CORONARY ARTERY. THE
SUBJECT WAS HOSPITALIZED
UNTIL 25OCT2020.
CONCOMITANT MEDICATIONS
WERE STARTED AND A
CORONARY BYPASS SURGERY
HAS BEEN SCHEDULED FOR
02NOV2020. THE SUBJECT IS
SCHEDULED TO RECEIVE DOSE
2 OF STUDY INTERVENTION ON
20NOV2020.

EKG ON 30OCT2020 REVEALED
SINUS BRADYCARDIA, SEPTAL
INFARCT, NONSPECIFIC ST AND
T WAVE ABNORMALITY.

CT CORONARY ANGIOGRAPHY
ON 23OCT2020 REVEALED
SEVERE 100% OCCLUSION OF
THE MID LAD AT THE
BIFURCATION OF THE FIRST
DIAGONAL ARTERY,
MODERATE STENOSIS OF THE
PROXIMAL RCA,
INCOMPLETELY EVALUATED
CYSTIC LESION WITHIN LEFT
KIDNEY.

CARDIAC CATHETERIZATION
ON 27OCT2020 REVEALED CTO
OF LAD WITH COLLETERALS
FROM RCA AND FLOW
VISUALIZED IN LAD ON RCC
INJECTION, NON DOMINANT
SMALL LCX, MILD RCA
DISEASE.

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

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

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

AEID	
Adverse event	CONGESTIVE HEART FAILURE
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)	23 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 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 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

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US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

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)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

AEID	USA-US201-2020-MRNA-1273-P30 1000001
Adverse event	PULMONARY THROMBOEMBOLISM
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)	6 NOV 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 type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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)	6 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	10 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

PT WAS DISCHARGED FROM
HOSPITAL ON 06NOV2020
FOLLOWING HOSPITALIZATION
FOR CABG PROCEDURE. LATER
THAT EVENING, PT
EXPERIENCED SHORTNESS OF
BREATH AND WAS SEEN IN
EMERGENCY DEPARTMENT. PT
WAS DIAGNOSED WITH
PULMONARY
THROMBOEMBOLISM AND
WAS ADMITTED TO HOSPITAL.
PT WAS STARTED ON IV
HEPARIN, THEN TRANSITIONED
TO ELIQUIS. PT WAS
DISCHARGED TO HOME ON
10NOV2020.

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

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

AEID

Adverse event

POST CORONARY ARTERY
BYPASS GRAFT PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

2 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

AEID

Adverse event

WORSENING OF MIDSTERNAL
CHEST PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

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	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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

AEID	
Adverse event	CYSTIC LESION WITHIN LEFT KIDNEY
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)	23 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	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

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	True
Concomitant Medication	False
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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:54:31

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

Yes ☒

No ☐

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

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	ATORVASTATIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPERLIPIDEMIA
Dose per administration	20
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 checked="" 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 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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

	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)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	23 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROIDISM
Dose per administration	85
Dose unit	mg <input type="radio"/> ug <input checked="" 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 checked="" 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 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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

	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)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	23 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	TAMSULOSIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	.4
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

	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)		UN SEP 2018
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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	IPRATROPIUM BROMIDE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
Dose per administration	2
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	SPRAYS
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 type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	LOSARTAN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CONGESTIVE HEART FAILURE
Dose per administration	25
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 checked="" 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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

	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)		24 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)		6 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	METOPROLOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CONGESTIVE HEART FAILURE
Dose per administration	25
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 checked="" 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 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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

	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)		24 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	ATORVASTATIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	CORONARY ARTERY DISEASE
Dose per administration	40
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 checked="" 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 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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

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)	24 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	HYPOTHYROIDISM
Dose per administration	88
Dose unit	mg <input type="radio"/> ug <input checked="" 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 checked="" 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 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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

	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)		24 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	HEPARIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PULMONARY THROMBOEMBOLISM
Dose per administration	UNK
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	UNKNOWN
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 type="radio"/> once <input type="radio"/> unknown <input checked="" type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
<hr/>		
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)		UN NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	APIXABAN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PULMONARY THROMBOEMBOLISM
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 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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

	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)	UN NOV 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	ASPIRIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ANTI-COAGULATION POST CABG
Dose per administration	81
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 checked="" 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 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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

	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)		UN NOV 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	OXYCODONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	POST CABG PAIN
Dose per administration	5
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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

	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)	UN NOV 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 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" 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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	PNEUMOVAX
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PNEUMONIA PHOPHYLAXIS
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	INJECTION
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 type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

	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)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" 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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	SODIUM CHLORIDE FLUSH
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CORONARY ARTERY DISEASE
Dose per administration	10
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" 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 type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

	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 checked="" 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)		23 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)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" 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"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

Name of Medication	SODIUM CHLORIDE 0.9% BOLUS
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CORONARY ARTERY DISEASE
Dose per administration	333.55
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" 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 type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 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)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" 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"/>

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:54:31

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:54:31

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
2 NOV 2020	CORONARY ARTERY BYPASS GRAFT	Adverse Event	

US3282113

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:54:31

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

US3282113

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:54:31

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 ☐

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:54:31

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/OCT/2020 16:23
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

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:54:31

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/NOV/2020 14:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:54:31

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	17/NOV/2020 19:05
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

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:54:31

SAEID	USA-US201-2020-MRNA-1273-P301000001
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	SHANE
Investigator's Last Name	CHRISTENSEN
Site Address: Street	6360 SOUTH 3000 EAST
Site Address: City	SALT LAKE CITY
Site Address: State	UT
Site Address: Postal Code	84121
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	24/NOV/2020 11:31
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

US3282113 (Prod: Foothill Family Clinic-South Clinic)

US3282113

Form: Participant Creation

Generated On: 26 Nov 2020 10:54:31

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3282113'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	16 Oct 2020 21:38:29

US3282113

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	16 Oct 2020 22:43:54

US3282113

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Oct 2020 21:38:30

US3282113

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jessica Shaw (b) (4)	16 Oct 2020 22:43:54

US3282113

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	16 Oct 2020 22:43:54

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Oct 2020 21:38:31

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Age](#)

Audit	User	Time (GMT)
User entered '66'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '66'	System	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Sex](#)

Audit	User	Time (GMT)
User entered 'Male (M)'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jessica Shaw (b) (4) [REDACTED] [REDACTED]	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

White

Audit	User	Time (GMT)
User entered '1'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:54:31

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:40

US3282113

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Oct 2020'	System	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2020'	System	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 4 (4)'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 22:44:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 22:44:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Shaw (b) (4) [REDACTED]	16 Oct 2020 22:44:59
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 22:44:53
User entered empty.	Jessica Shaw (b) (4) [REDACTED]	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:53

US3282113

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	16 Oct 2020 21:38:30

US3282113

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:54:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:54:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:13:34

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:55:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:55:35
Data point term sent to Coder	System	17 Oct 2020 01:14:34
User entered 'hyperlipidemia'	dylan owen (b) (4)	17 Oct 2020 01:14:01
	(b) (4)	

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2017'	System	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 01:14:01

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:08:27
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'updated conmeds' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 15:18:35
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:10:26
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:55:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:55:35
Data point term sent to Coder	System	17 Oct 2020 01:14:34
User entered 'hypothyroidism'	dylan owen (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	17 Oct 2020 01:17:09
User entered 'Yes (Y)' reason for change: Data Entry Error	dylan owen (b) (4)	17 Oct 2020 01:17:09
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	
User entered 'No (N)'	System	17 Oct 2020 01:14:23
	dylan owen (b) (4)	17 Oct 2020 01:14:23
	(b) (4)	

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2017'	System	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 01:14:23

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:55:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:55:36
Data point term sent to Coder	System	17 Oct 2020 01:15:34
User entered 'benign prostatic hyperplasia'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un Sep 2018'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Sep 2018'	System	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2018'	System	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 01:14:46

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

Condition

Audit	User	Time (GMT)
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)	17 Oct 2020 09:55:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:55:36
Data point term sent to Coder	System	17 Oct 2020 01:17:35
User entered 'seasonal allergies'	dylan owen (b) (4)	17 Oct 2020 01:16:36
	(b) (4)	

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2015'	System	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 01:16:36

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:23:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 17:23:01
Data point term sent to Coder	System	24 Nov 2020 15:51:21
User closed query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term.' (Site from System).	System	24 Nov 2020 15:51:17
Query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term.' answered with 'clarified' (Site from System).	Jessica Shaw (b) (4) (b) (4)	24 Nov 2020 15:51:17
User entered 'INTERMITTENT MIDSTERNAL CHEST PAIN, cardiac' reason for change: Data Entry Error	Jessica Shaw (b) (4) (b) (4)	24 Nov 2020 15:51:03
User opened query 'DM-Coding: Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term.' (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 08:30:05
Data point term sent to Coder	System	23 Nov 2020 18:53:23
User entered 'intermittent midsternal chest pain'	Jessica Shaw (b) (4) (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '02 Nov 2020'	Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2010'	System	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Nov 2020'	System	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2020'	System	23 Nov 2020 18:52:29

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:04:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:04:07
Data point term sent to Coder	System	23 Nov 2020 18:57:31
User entered 'obstructive sleep apnea'	Jessica Shaw (b) (4) (b) (4) (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '2014'	System	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:56:54

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '15:12'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 15:12'	System	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '71.0' in	dylan owen (b) (4)	17 Oct 2020 01:18:59
DataPoint set to visible.	(b) (4) System	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '214.6' lb	dylan owen (b) (4)	17 Oct 2020 01:18:59
DataPoint set to visible.	(b) (4) System	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '29.99321'	System	17 Oct 2020 01:18:59
DataPoint set to visible.	System	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	17 Oct 2020 01:18:59
DataPoint set to visible.	System	16 Oct 2020 22:59:18

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: If Screening and dosing (V1D1) are done on the same day (16-OCT-2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 15:02:07
Query 'Per CDM: If Screening and dosing (V1D1) are done on the same day (16-OCT-2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	22 Oct 2020 15:16:00
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User opened query 'Per CDM: If Screening and dosing (V1D1) are done on the same day (16-OCT-2020) then Temperature, 'Pulse, Respiratory Rate, Systolic BP, and Diastolic BP should be marked as "Not Done" using the drop down list of options for the data fields concerned. Please update these fields as per CCGs.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 13:59:35
User entered '98.7' F	dylan owen (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User entered 'Oral (Oral)'	dylan owen (b) (4)	17 Oct 2020 01:18:59
	(b) (4)	

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User entered '62'	dylan owen (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User entered '16'	dylan owen (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User entered '124'	dylan owen (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	22 Oct 2020 15:15:55
User entered '84'	dylan owen (b) (4)	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Oct 2020 01:18:59

US3282113

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:19:18

US3282113

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:19:18

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

[Specify](#)

Audit	User	Time (GMT)
User entered 'microbiology lab with about 65 other staff members'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'I'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

[Other](#)

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:54:31

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:23:47

US3282113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:08

US3282113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:08

US3282113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:08

US3282113

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	16 Oct 2020 22:59:08

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	16 Oct 2020 21:38:36

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '191382'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	16 Oct 2020 21:38:36

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	16 Oct 2020 21:38:36

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:15

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:15

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:15

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:15

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Oct 2020 22:44:15

US3282113

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4)	17 Oct 2020 01:24:08
DataPoint set to visible.	(b) (4) System	16 Oct 2020 22:44:53

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:27:06
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:39
User entered '71.0' in	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Weight

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:27:16
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:45
User entered '214.6' lb	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:27:06
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:39
User entered '71.0' in	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Weight

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:27:16
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:45
User entered '214.6' lb	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '15:12'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 15:12'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.7' F	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Pulse (xxx)

Audit	User	Time (GMT)
User entered '62'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:27:06
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:39
User entered '71.0' in	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:54:31

Weight

Audit	User	Time (GMT)
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 20:27:16
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' answered with 'corrected' (Site from DM).	Jessica Shaw (b) (4)	23 Oct 2020 14:47:22
User entered missing code ND - Not Done; reason for change Data Entry Error	Jessica Shaw (b) (4)	23 Oct 2020 14:47:09
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:23:45
User entered '214.6' lb	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16:59'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 16:59'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.6' F	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '61'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Oct 2020 01:26:03

US3282113

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:17

US3282113

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:26:17

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16:20'	Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 16:20'	System	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Rachel Pugmire (b) (4) (b) (4)	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 22:59:39

US3282113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:05

US3282113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:05

US3282113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:33'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:05

US3282113

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 15:33'	System	17 Oct 2020 01:27:05

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	dylan owen (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '15:30'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '16 Oct 2020 15:30'	System	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	dylan owen (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 01:27:29

US3282113

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	17 Oct 2020 01:27:41

US3282113

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Oct 2020 01:27:41

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:04:14', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a3db13d3-2786-4b2b-afcb-6f124f905a99'	System	16 Oct 2020 23:04:50
User entered 'Yes (Y)'	System	16 Oct 2020 23:04:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:04:25', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a3db13d3-2786-4b2b-afcb-6f124f905a99'	System	16 Oct 2020 23:04:50
User entered '97.6'	System	16 Oct 2020 23:04:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:04:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a3db13d3-2786-4b2b-afcb-6f124f905a99'	System	16 Oct 2020 23:04:50
User entered 'No (N)'	System	16 Oct 2020 23:04:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:04:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a3db13d3-2786-4b2b-afcb-6f124f905a99'	System	16 Oct 2020 23:04:50
User entered '16 Oct 2020 17:04'	System	16 Oct 2020 23:04:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 16:40'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 19:10'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 20:05'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 2'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:41:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dc956ff5-e343-4d08-ab80-163031597668'	System	18 Oct 2020 07:41:31
User entered 'Yes (Y)'	System	18 Oct 2020 07:41:31

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:41:13', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dc956ff5-e343-4d08-ab80-163031597668' User entered '97.1'	System	18 Oct 2020 07:41:31
	System	18 Oct 2020 07:41:31

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:41:23', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dc956ff5-e343-4d08-ab80-163031597668'	System	18 Oct 2020 07:41:31
User entered 'No (N)'	System	18 Oct 2020 07:41:31

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:41:29', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'dc956ff5-e343-4d08-ab80-163031597668' User entered '18 Oct 2020 01:41'	System	18 Oct 2020 07:41:31
	System	18 Oct 2020 07:41:31

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 3'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:32:23', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '81a8f6ff-ab01-4e58-893b-ac8ffbf846f'	System	19 Oct 2020 01:32:56
User entered 'Yes (Y)'	System	19 Oct 2020 01:32:56

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:32:39', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '81a8f6ff-ab01-4e58-893b-ac8ffbf846f' User entered '97.3'	System	19 Oct 2020 01:32:56

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:32:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '81a8f6ff-ab01-4e58-893b-ac8ffbf846f'	System	19 Oct 2020 01:32:56
User entered 'No (N)'	System	19 Oct 2020 01:32:56

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:32:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '81a8f6ff-ab01-4e58-893b-ac8ffbf846f'	System	19 Oct 2020 01:32:56
User entered '18 Oct 2020 19:32'	System	19 Oct 2020 01:32:56

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 4'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:10', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9467b855-56ad-4bf9-8b75-23357d3d18bf'	System	19 Oct 2020 18:50:30
User entered 'Yes (Y)'	System	19 Oct 2020 18:50:30

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:18', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9467b855-56ad-4bf9-8b75-23357d3d18bf' User entered '99.3'	System	19 Oct 2020 18:50:30
	System	19 Oct 2020 18:50:30

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9467b855-56ad-4bf9-8b75-23357d3d18bf'	System	19 Oct 2020 18:50:30
User entered 'No (N)'	System	19 Oct 2020 18:50:30

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:27', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9467b855-56ad-4bf9-8b75-23357d3d18bf' User entered '19 Oct 2020 12:50'	System	19 Oct 2020 18:50:30
	System	19 Oct 2020 18:50:30

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 5'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:14:50', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '35b07c8c-bea2-4771-bfbc-567206b1596c' User entered 'Yes (Y)'	System	21 Oct 2020 01:15:06
	System	21 Oct 2020 01:15:06

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:14:57', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '35b07c8c-bea2-4771-bfbc-567206b1596c' User entered '97.9'	System	21 Oct 2020 01:15:06
	System	21 Oct 2020 01:15:06

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:01', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '35b07c8c-bea2-4771-bfbc-567206b1596c' User entered 'No (N)'	System	21 Oct 2020 01:15:06
	System	21 Oct 2020 01:15:06

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:05', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '35b07c8c-bea2-4771-bfbc-567206b1596c' User entered '20 Oct 2020 19:15'	System	21 Oct 2020 01:15:06
	System	21 Oct 2020 01:15:06

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 6'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:09:33', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '45f11fea-fa02-4b6d-942f-c855e2644ae0'	System	21 Oct 2020 18:09:50
User entered 'Yes (Y)'	System	21 Oct 2020 18:09:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:09:41', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '45f11fea-fa02-4b6d-942f-c855e2644ae0' User entered '97.2'	System	21 Oct 2020 18:09:50
	System	21 Oct 2020 18:09:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:09:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '45f11fea-fa02-4b6d-942f-c855e2644ae0'	System	21 Oct 2020 18:09:50
User entered 'No (N)'	System	21 Oct 2020 18:09:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:09:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '45f11fea-fa02-4b6d-942f-c855e2644ae0' User entered '21 Oct 2020 12:09'	System	21 Oct 2020 18:09:50
	System	21 Oct 2020 18:09:50

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 7'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:03:56', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '517b8685-248c-44fc-8f84-af1dca462e28'	System	22 Oct 2020 23:04:18
User entered 'Yes (Y)'	System	22 Oct 2020 23:04:18

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '517b8685-248c-44fc-8f84-af1dca462e28'	System	22 Oct 2020 23:04:18
User entered '97.2'	System	22 Oct 2020 23:04:18

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:10', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '517b8685-248c-44fc-8f84-af1dca462e28'	System	22 Oct 2020 23:04:18
User entered 'No (N)'	System	22 Oct 2020 23:04:18

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '517b8685-248c-44fc-8f84-af1dca462e28'	System	22 Oct 2020 23:04:18
User entered '22 Oct 2020 17:04'	System	22 Oct 2020 23:04:18

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:05:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '984cb130-59ff-4056-a0a0-4326d23a2902'	System	16 Oct 2020 23:06:09
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 23:06:09

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:05:35', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '984cb130-59ff-4056-a0a0-4326d23a2902'	System	16 Oct 2020 23:06:09
User entered 'No (N)'	System	16 Oct 2020 23:06:09

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:05:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '984cb130-59ff-4056-a0a0-4326d23a2902'	System	16 Oct 2020 23:06:09
User entered 'No (N)'	System	16 Oct 2020 23:06:09

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:03', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '984cb130-59ff-4056-a0a0-4326d23a2902'	System	16 Oct 2020 23:06:09
User entered 'None (1)'	System	16 Oct 2020 23:06:09

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '984cb130-59ff-4056-a0a0-4326d23a2902'	System	16 Oct 2020 23:06:09
User entered '16 Oct 2020 17:06'	System	16 Oct 2020 23:06:09

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 16:40'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 19:10'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 20:05'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 2'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:41:39', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '36a56496-de28-4034-8905-b9d79908b631'	System	18 Oct 2020 07:42:37
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 07:42:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:42:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '36a56496-de28-4034-8905-b9d79908b631'	System	18 Oct 2020 07:42:37
User entered 'No (N)'	System	18 Oct 2020 07:42:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:42:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '36a56496-de28-4034-8905-b9d79908b631'	System	18 Oct 2020 07:42:37
User entered 'No (N)'	System	18 Oct 2020 07:42:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:42:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '36a56496-de28-4034-8905-b9d79908b631'	System	18 Oct 2020 07:42:37
User entered 'None (1)'	System	18 Oct 2020 07:42:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:42:35', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '36a56496-de28-4034-8905-b9d79908b631' User entered '18 Oct 2020 01:42'	System	18 Oct 2020 07:42:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 3'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '6797a0fb-d9d3-4fb4-894c-ff99b5b272e9'	System	19 Oct 2020 01:33:33
User entered 'None (1)'	System	19 Oct 2020 01:33:33

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '6797a0fb-d9d3-4fb4-894c-ff99b5b272e9'	System	19 Oct 2020 01:33:33
User entered 'No (N)'	System	19 Oct 2020 01:33:33

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '6797a0fb-d9d3-4fb4-894c-ff99b5b272e9'	System	19 Oct 2020 01:33:33
User entered 'No (N)'	System	19 Oct 2020 01:33:33

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '6797a0fb-d9d3-4fb4-894c-ff99b5b272e9' User entered 'None (1)'	System	19 Oct 2020 01:33:33
	System	19 Oct 2020 01:33:33

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:29', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '6797a0fb-d9d3-4fb4-894c-ff99b5b272e9' User entered '18 Oct 2020 19:33'	System	19 Oct 2020 01:33:33
	System	19 Oct 2020 01:33:33

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 4'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:41', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'fbcca87a-749e-479e-95e4-9548ecee72bd' User entered 'None (1)'	System	19 Oct 2020 18:51:02
	System	19 Oct 2020 18:51:02

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:44', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'fbcca87a-749e-479e-95e4-9548ecee72bd'	System	19 Oct 2020 18:51:02
User entered 'No (N)'	System	19 Oct 2020 18:51:02

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:50', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'fbcca87a-749e-479e-95e4-9548ecee72bd'	System	19 Oct 2020 18:51:02
User entered 'No (N)'	System	19 Oct 2020 18:51:02

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'fbcca87a-749e-479e-95e4-9548ecee72bd' User entered 'None (1)'	System	19 Oct 2020 18:51:02
	System	19 Oct 2020 18:51:02

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:50:57', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'fbcca87a-749e-479e-95e4-9548ecee72bd' User entered '19 Oct 2020 12:50'	System	19 Oct 2020 18:51:02
	System	19 Oct 2020 18:51:02

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 5'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c2d0d988-fe0d-4a96-8447-79ae4a3343d5'	System	21 Oct 2020 01:15:37
User entered 'None (1)'	System	21 Oct 2020 01:15:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:16', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c2d0d988-fe0d-4a96-8447-79ae4a3343d5' User entered 'No (N)'	System	21 Oct 2020 01:15:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:20', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c2d0d988-fe0d-4a96-8447-79ae4a3343d5' User entered 'No (N)'	System	21 Oct 2020 01:15:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:28', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c2d0d988-fe0d-4a96-8447-79ae4a3343d5'	System	21 Oct 2020 01:15:37
User entered 'None (1)'	System	21 Oct 2020 01:15:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c2d0d988-fe0d-4a96-8447-79ae4a3343d5' User entered '20 Oct 2020 19:15'	System	21 Oct 2020 01:15:37
	System	21 Oct 2020 01:15:37

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 6'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '07d7d42a-e099-4d0f-893c-c0128e2b8095'	System	21 Oct 2020 18:10:20
User entered 'None (1)'	System	21 Oct 2020 18:10:20

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '07d7d42a-e099-4d0f-893c-c0128e2b8095'	System	21 Oct 2020 18:10:20
User entered 'No (N)'	System	21 Oct 2020 18:10:20

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:10', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '07d7d42a-e099-4d0f-893c-c0128e2b8095'	System	21 Oct 2020 18:10:20
User entered 'No (N)'	System	21 Oct 2020 18:10:20

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '07d7d42a-e099-4d0f-893c-c0128e2b8095' User entered 'None (1)'	System	21 Oct 2020 18:10:20
	System	21 Oct 2020 18:10:20

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:19', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '07d7d42a-e099-4d0f-893c-c0128e2b8095'	System	21 Oct 2020 18:10:20
User entered '21 Oct 2020 12:10'	System	21 Oct 2020 18:10:20

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 7'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '63bcbcd9-4232-442f-ada5-1ca6b2c940cf'	System	22 Oct 2020 23:04:40
User entered 'None (1)'	System	22 Oct 2020 23:04:40

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:25', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '63bcbcd9-4232-442f-ada5-1ca6b2c940cf'	System	22 Oct 2020 23:04:40
User entered 'No (N)'	System	22 Oct 2020 23:04:40

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '63bcbcd9-4232-442f-ada5-1ca6b2c940cf'	System	22 Oct 2020 23:04:40
User entered 'No (N)'	System	22 Oct 2020 23:04:40

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '63bcbcd9-4232-442f-ada5-1ca6b2c940cf' User entered 'None (1)'	System	22 Oct 2020 23:04:40
	System	22 Oct 2020 23:04:40

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '63bcbcd9-4232-442f-ada5-1ca6b2c940cf' User entered '22 Oct 2020 17:04'	System	22 Oct 2020 23:04:40
	System	22 Oct 2020 23:04:40

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:13', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'None (0)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'None (0)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951'	System	16 Oct 2020 23:07:10
User entered 'None (0)'	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:42', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'None (0)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951'	System	16 Oct 2020 23:07:10
User entered 'None (0)'	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:06:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered 'None (0)'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:07:05', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951'	System	16 Oct 2020 23:07:10
User entered 'No (N)'	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-16T17:07:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '57b91c47-2d3d-43d0-a9b9-1fe8fc185951' User entered '16 Oct 2020 17:07'	System	16 Oct 2020 23:07:10
	System	16 Oct 2020 23:07:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 16:40'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 19:10'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 20:05'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 2'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:01', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201'	System	18 Oct 2020 07:43:47
User entered 'No interference with activity (1)'	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201'	System	18 Oct 2020 07:43:47
User entered 'None (0)'	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:14', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201'	System	18 Oct 2020 07:43:47
User entered 'None (0)'	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:20', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201'	System	18 Oct 2020 07:43:47
User entered 'None (0)'	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:25', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201'	System	18 Oct 2020 07:43:47
User entered 'None (0)'	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201'	System	18 Oct 2020 07:43:47
User entered 'None (0)'	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201'	System	18 Oct 2020 07:43:47
User entered 'No (N)'	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T01:43:44', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7bf0499-58f1-4534-b11f-a573f8157201'	System	18 Oct 2020 07:43:47
User entered '18 Oct 2020 01:43'	System	18 Oct 2020 07:43:47

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 3'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509'	System	19 Oct 2020 01:34:49
User entered 'None (0)'	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:33:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509'	System	19 Oct 2020 01:34:49
User entered 'None (0)'	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509'	System	19 Oct 2020 01:34:49
User entered 'None (0)'	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:17', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509'	System	19 Oct 2020 01:34:49
User entered 'None (0)'	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:21', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509'	System	19 Oct 2020 01:34:49
User entered 'None (0)'	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509'	System	19 Oct 2020 01:34:49
User entered 'None (0)'	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:41', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509'	System	19 Oct 2020 01:34:49
User entered 'No (N)'	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-18T19:34:44', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3cd1d445-249c-4a0d-acd0-980493493509'	System	19 Oct 2020 01:34:49
User entered '18 Oct 2020 19:34'	System	19 Oct 2020 01:34:49

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 4'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834'	System	19 Oct 2020 18:51:54
User entered 'None (0)'	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834'	System	19 Oct 2020 18:51:54
User entered 'None (0)'	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834'	System	19 Oct 2020 18:51:54
User entered 'None (0)'	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834'	System	19 Oct 2020 18:51:54
User entered 'None (0)'	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:39', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834'	System	19 Oct 2020 18:51:54
User entered 'None (0)'	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:41', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834'	System	19 Oct 2020 18:51:54
User entered 'None (0)'	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:47', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834' User entered 'No (N)'	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-19T12:51:51', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '9f5f721e-5c2d-44a3-a470-5c02a5960834' User entered '19 Oct 2020 12:51'	System	19 Oct 2020 18:51:54
	System	19 Oct 2020 18:51:54

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 5'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82'	System	21 Oct 2020 01:16:18
User entered 'None (0)'	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82'	System	21 Oct 2020 01:16:18
User entered 'None (0)'	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:53', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82'	System	21 Oct 2020 01:16:18
User entered 'None (0)'	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:15:57', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82'	System	21 Oct 2020 01:16:18
User entered 'None (0)'	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:16:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82'	System	21 Oct 2020 01:16:18
User entered 'None (0)'	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:16:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82'	System	21 Oct 2020 01:16:18
User entered 'None (0)'	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:16:13', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82'	System	21 Oct 2020 01:16:18
User entered 'No (N)'	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-20T19:16:16', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e5abebd6-5d74-4234-82ea-b13547027a82'	System	21 Oct 2020 01:16:18
User entered '20 Oct 2020 19:16'	System	21 Oct 2020 01:16:18

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 6'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:23', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'None (0)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:28', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'None (0)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:33', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'None (0)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538' User entered 'None (0)'	System	21 Oct 2020 18:11:07
	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:42', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'None (0)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:10:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'None (0)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:11:02', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered 'No (N)'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-21T12:11:05', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '87109353-f859-45fc-a654-5f9cfb021538'	System	21 Oct 2020 18:11:07
User entered '21 Oct 2020 12:11'	System	21 Oct 2020 18:11:07

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Oct 2020 22:59:39
User entered 'Day 7'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:42', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3'	System	22 Oct 2020 23:05:10
User entered 'None (0)'	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:48', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3'	System	22 Oct 2020 23:05:10
User entered 'None (0)'	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:51', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3'	System	22 Oct 2020 23:05:10
User entered 'None (0)'	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3' User entered 'None (0)'	System	22 Oct 2020 23:05:10
	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:04:57', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3'	System	22 Oct 2020 23:05:10
User entered 'None (0)'	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:05:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3'	System	22 Oct 2020 23:05:10
User entered 'None (0)'	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:05:04', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3' User entered 'No (N)'	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-10-22T17:05:07', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'b3d2559b-baa2-4dba-8e27-f63c48ded2e3'	System	22 Oct 2020 23:05:10
User entered '22 Oct 2020 17:05'	System	22 Oct 2020 23:05:10

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 22:59:39

US3282113

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 22:59:39

US3282113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:44

US3282113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:44

US3282113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:44

US3282113

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:18:44

US3282113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:47

US3282113

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 15:18:47

US3282113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	09 Nov 2020 18:56:04

US3282113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '30 Oct 2020'	Jessica Shaw (b) (4)	09 Nov 2020 18:56:04

US3282113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jessica Shaw (b) (4)	09 Nov 2020 18:56:04

US3282113

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	09 Nov 2020 18:56:04

US3282113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	09 Nov 2020 18:56:08

US3282113

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 18:56:08

US3282113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	09 Nov 2020 18:56:27

US3282113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '9 Nov 2020'	Jessica Shaw (b) (4)	09 Nov 2020 18:56:27

US3282113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jessica Shaw (b) (4)	09 Nov 2020 18:56:27

US3282113

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:54:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	09 Nov 2020 18:56:27

US3282113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	09 Nov 2020 18:56:32

US3282113

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Nov 2020 18:56:32

US3282113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:25:33

US3282113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '19 Nov 2020'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:25:33

US3282113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:25:33

US3282113

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:54:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	19 Nov 2020 19:25:33

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '11:08'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 11:08'	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '18'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '84'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 20:17:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 20:17:04
User entered 'Yes (Y)' reason for change: Data Entry Error	dylan owen (b) (4) (b) (4)	19 Nov 2020 20:17:04
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 19:54:40
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	dylan owen (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '13:07' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	dylan owen (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 13:07'	System	19 Nov 2020 20:17:04
User entered empty.	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.5' F reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	dylan owen (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	dylan owen (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	dylan owen (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Nov 2020 20:17:04
User entered empty.	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '14' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	dylan owen (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Nov 2020 20:17:04
User entered empty.	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '130' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	dylan owen (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 20:17:04
User entered empty.	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '79' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 20:17:04
User entered empty.	dylan owen (b) (4)	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:54:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Nov 2020 20:17:04
User entered empty.	System	19 Nov 2020 19:54:40

US3282113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 00:45:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Nov 2020 00:45:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessica Shaw (b) (4) [REDACTED]	20 Nov 2020 00:45:49
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 19:54:55
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:55

US3282113

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:54:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:54:55

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '12:37'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 12:37'	System	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:54:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	19 Nov 2020 19:50:23

US3282113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:56:53

US3282113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:56:53

US3282113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:40'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:56:53

US3282113

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 11:40'	System	19 Nov 2020 19:56:53

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:54:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '11:45'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '19 Nov 2020 11:45'	System	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 19:57:48

US3282113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 19:58:01

US3282113

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:54:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 19:58:01

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:08:36', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c699fd9d-ef9f-4092-83e7-e11e045b14be'	System	19 Nov 2020 20:08:57
User entered 'Yes (Y)'	System	19 Nov 2020 20:08:57

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:08:43', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c699fd9d-ef9f-4092-83e7-e11e045b14be'	System	19 Nov 2020 20:08:57
User entered '98.5'	System	19 Nov 2020 20:08:57

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:08:50', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c699fd9d-ef9f-4092-83e7-e11e045b14be'	System	19 Nov 2020 20:08:57
User entered 'No (N)'	System	19 Nov 2020 20:08:57

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:08:53', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c699fd9d-ef9f-4092-83e7-e11e045b14be' User entered '19 Nov 2020 13:08'	System	19 Nov 2020 20:08:57
	System	19 Nov 2020 20:08:57

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 12:57'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 15:27'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:28:47', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '638476ba-e141-4ba4-bb3c-a829138e752c'	System	19 Nov 2020 23:29:13
User entered 'Yes (Y)'	System	19 Nov 2020 23:29:13

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:28:58', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '638476ba-e141-4ba4-bb3c-a829138e752c'	System	19 Nov 2020 23:29:13
User entered '97.9'	System	19 Nov 2020 23:29:13

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:29:05', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '638476ba-e141-4ba4-bb3c-a829138e752c'	System	19 Nov 2020 23:29:13
User entered 'No (N)'	System	19 Nov 2020 23:29:13

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:29:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '638476ba-e141-4ba4-bb3c-a829138e752c' User entered '19 Nov 2020 16:29'	System	19 Nov 2020 23:29:13
	System	19 Nov 2020 23:29:13

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 16:22'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 2'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 3'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:17', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '92728a63-f4b3-474e-b833-5d612718455f'	System	22 Nov 2020 01:03:39
User entered 'Yes (Y)'	System	22 Nov 2020 01:03:39

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '92728a63-f4b3-474e-b833-5d612718455f'	System	22 Nov 2020 01:03:39
User entered '97.4'	System	22 Nov 2020 01:03:39

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '92728a63-f4b3-474e-b833-5d612718455f'	System	22 Nov 2020 01:03:39
User entered 'No (N)'	System	22 Nov 2020 01:03:39

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '92728a63-f4b3-474e-b833-5d612718455f'	System	22 Nov 2020 01:03:39
User entered '21 Nov 2020 18:03'	System	22 Nov 2020 01:03:39

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 4'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '022013f1-91ca-43dd-9c56-85b5406a68d1'	System	22 Nov 2020 19:14:47
User entered 'Yes (Y)'	System	22 Nov 2020 19:14:47

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:39', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '022013f1-91ca-43dd-9c56-85b5406a68d1'	System	22 Nov 2020 19:14:47
User entered '97.9'	System	22 Nov 2020 19:14:47

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:42', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '022013f1-91ca-43dd-9c56-85b5406a68d1'	System	22 Nov 2020 19:14:47
User entered 'No (N)'	System	22 Nov 2020 19:14:47

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '022013f1-91ca-43dd-9c56-85b5406a68d1'	System	22 Nov 2020 19:14:47
User entered '22 Nov 2020 12:14'	System	22 Nov 2020 19:14:47

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 5'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:34:47', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1d7ea61d-a764-44e7-8f8f-e20864c90935'	System	23 Nov 2020 19:35:14
User entered 'Yes (Y)'	System	23 Nov 2020 19:35:14

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1d7ea61d-a764-44e7-8f8f-e20864c90935'	System	23 Nov 2020 19:35:14
User entered '98.3'	System	23 Nov 2020 19:35:14

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:09', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1d7ea61d-a764-44e7-8f8f-e20864c90935'	System	23 Nov 2020 19:35:14
User entered 'No (N)'	System	23 Nov 2020 19:35:14

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '1d7ea61d-a764-44e7-8f8f-e20864c90935' User entered '23 Nov 2020 12:35'	System	23 Nov 2020 19:35:14
	System	23 Nov 2020 19:35:14

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 6'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:58:56', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7228769-e05c-4f33-9994-c72944a7d5be'	System	25 Nov 2020 04:59:18
User entered 'Yes (Y)'	System	25 Nov 2020 04:59:18

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:03', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7228769-e05c-4f33-9994-c72944a7d5be'	System	25 Nov 2020 04:59:18
User entered '98.2'	System	25 Nov 2020 04:59:18

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7228769-e05c-4f33-9994-c72944a7d5be'	System	25 Nov 2020 04:59:18
User entered 'No (N)'	System	25 Nov 2020 04:59:18

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:14', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e7228769-e05c-4f33-9994-c72944a7d5be'	System	25 Nov 2020 04:59:18
User entered '24 Nov 2020 21:59'	System	25 Nov 2020 04:59:18

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 7'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:09:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bca3c16e-7aa8-46db-ae53-310453248f90'	System	19 Nov 2020 20:10:10
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 20:10:10

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:09:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bca3c16e-7aa8-46db-ae53-310453248f90'	System	19 Nov 2020 20:10:10
User entered 'No (N)'	System	19 Nov 2020 20:10:10

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:09:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bca3c16e-7aa8-46db-ae53-310453248f90'	System	19 Nov 2020 20:10:10
User entered 'No (N)'	System	19 Nov 2020 20:10:10

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:02', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bca3c16e-7aa8-46db-ae53-310453248f90'	System	19 Nov 2020 20:10:10
User entered 'None (1)'	System	19 Nov 2020 20:10:10

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bca3c16e-7aa8-46db-ae53-310453248f90'	System	19 Nov 2020 20:10:10
User entered '19 Nov 2020 13:10'	System	19 Nov 2020 20:10:10

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 12:57'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 15:27'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:29:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ca67c752-52ca-4cdf-95c5-869d26a77b7a'	System	19 Nov 2020 23:30:49
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 23:30:49

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:30:20', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ca67c752-52ca-4cdf-95c5-869d26a77b7a'	System	19 Nov 2020 23:30:49
User entered 'No (N)'	System	19 Nov 2020 23:30:49

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:30:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ca67c752-52ca-4cdf-95c5-869d26a77b7a'	System	19 Nov 2020 23:30:49
User entered 'No (N)'	System	19 Nov 2020 23:30:49

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:30:35', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ca67c752-52ca-4cdf-95c5-869d26a77b7a' User entered 'None (1)'	System	19 Nov 2020 23:30:49

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:30:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'ca67c752-52ca-4cdf-95c5-869d26a77b7a' User entered '19 Nov 2020 16:30'	System	19 Nov 2020 23:30:49
	System	19 Nov 2020 23:30:49

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 16:22'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 2'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 3'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '5de1a797-d254-45ef-af71-7c78f18193dd'	System	22 Nov 2020 01:04:19
User entered 'Does not interfere with activity (2)'	System	22 Nov 2020 01:04:19

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:03:50', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '5de1a797-d254-45ef-af71-7c78f18193dd'	System	22 Nov 2020 01:04:19
User entered 'No (N)'	System	22 Nov 2020 01:04:19

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '5de1a797-d254-45ef-af71-7c78f18193dd'	System	22 Nov 2020 01:04:19
User entered 'No (N)'	System	22 Nov 2020 01:04:19

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '5de1a797-d254-45ef-af71-7c78f18193dd' User entered 'None (1)'	System	22 Nov 2020 01:04:19

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:16', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '5de1a797-d254-45ef-af71-7c78f18193dd' User entered '21 Nov 2020 18:04'	System	22 Nov 2020 01:04:19

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 4'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:52', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f4c46311-bf2b-4804-a031-b507d2210e4e'	System	22 Nov 2020 19:15:11
User entered 'None (1)'	System	22 Nov 2020 19:15:11

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:55', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f4c46311-bf2b-4804-a031-b507d2210e4e'	System	22 Nov 2020 19:15:11
User entered 'No (N)'	System	22 Nov 2020 19:15:11

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:14:58', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f4c46311-bf2b-4804-a031-b507d2210e4e'	System	22 Nov 2020 19:15:11
User entered 'No (N)'	System	22 Nov 2020 19:15:11

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:06', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f4c46311-bf2b-4804-a031-b507d2210e4e' User entered 'None (1)'	System	22 Nov 2020 19:15:11
	System	22 Nov 2020 19:15:11

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:09', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'f4c46311-bf2b-4804-a031-b507d2210e4e' User entered '22 Nov 2020 12:15'	System	22 Nov 2020 19:15:11
	System	22 Nov 2020 19:15:11

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 5'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:21', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c0dfc69c-685b-411d-acb6-62283e1348bf'	System	23 Nov 2020 19:35:44
User entered 'None (1)'	System	23 Nov 2020 19:35:44

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c0dfc69c-685b-411d-acb6-62283e1348bf'	System	23 Nov 2020 19:35:44
User entered 'No (N)'	System	23 Nov 2020 19:35:44

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:30', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c0dfc69c-685b-411d-acb6-62283e1348bf'	System	23 Nov 2020 19:35:44
User entered 'No (N)'	System	23 Nov 2020 19:35:44

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:36', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c0dfc69c-685b-411d-acb6-62283e1348bf' User entered 'None (1)'	System	23 Nov 2020 19:35:44
	System	23 Nov 2020 19:35:44

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'c0dfc69c-685b-411d-acb6-62283e1348bf' User entered '23 Nov 2020 12:35'	System	23 Nov 2020 19:35:44
	System	23 Nov 2020 19:35:44

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 6'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:19', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bb6cb4dc-e4e4-49b0-886e-02d3661b11a5'	System	25 Nov 2020 04:59:56
User entered 'None (1)'	System	25 Nov 2020 04:59:56

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:23', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bb6cb4dc-e4e4-49b0-886e-02d3661b11a5'	System	25 Nov 2020 04:59:56
User entered 'No (N)'	System	25 Nov 2020 04:59:56

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bb6cb4dc-e4e4-49b0-886e-02d3661b11a5'	System	25 Nov 2020 04:59:56
User entered 'No (N)'	System	25 Nov 2020 04:59:56

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:50', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bb6cb4dc-e4e4-49b0-886e-02d3661b11a5'	System	25 Nov 2020 04:59:56
User entered 'None (1)'	System	25 Nov 2020 04:59:56

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T21:59:54', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'bb6cb4dc-e4e4-49b0-886e-02d3661b11a5'	System	25 Nov 2020 04:59:56
User entered '24 Nov 2020 21:59'	System	25 Nov 2020 04:59:56

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 7'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec'	System	19 Nov 2020 20:10:49
User entered 'None (0)'	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:19', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec'	System	19 Nov 2020 20:10:49
User entered 'None (0)'	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:23', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec'	System	19 Nov 2020 20:10:49
User entered 'None (0)'	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:28', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec'	System	19 Nov 2020 20:10:49
User entered 'None (0)'	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:31', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec'	System	19 Nov 2020 20:10:49
User entered 'None (0)'	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:34', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec'	System	19 Nov 2020 20:10:49
User entered 'None (0)'	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:43', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec'	System	19 Nov 2020 20:10:49
User entered 'No (N)'	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T13:10:46', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'a8c39bad-cd92-43a1-9cf3-1db0c6006dec' User entered '19 Nov 2020 13:10'	System	19 Nov 2020 20:10:49
	System	19 Nov 2020 20:10:49

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 12:57'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 15:27'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 1, after vaccination (at home)'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:30:52', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'None (0)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:03', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'None (0)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:10', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'None (0)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'None (0)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:17', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'None (0)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:21', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'None (0)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:29', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3'	System	19 Nov 2020 23:31:39
User entered 'No (N)'	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-19T16:31:36', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'e28ffa1b-8025-4a80-894f-6dc0c2e419b3' User entered '19 Nov 2020 16:31'	System	19 Nov 2020 23:31:39
	System	19 Nov 2020 23:31:39

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020 16:22'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 2'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 3'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:32', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3'	System	22 Nov 2020 01:05:16
User entered 'None (0)'	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:36', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3'	System	22 Nov 2020 01:05:16
User entered 'None (0)'	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:47', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3'	System	22 Nov 2020 01:05:16
User entered 'None (0)'	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:04:51', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3'	System	22 Nov 2020 01:05:16
User entered 'None (0)'	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:05:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3'	System	22 Nov 2020 01:05:16
User entered 'None (0)'	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:05:03', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3'	System	22 Nov 2020 01:05:16
User entered 'None (0)'	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:05:09', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3'	System	22 Nov 2020 01:05:16
User entered 'No (N)'	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-21T18:05:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '3779ab22-9ae7-4e36-998b-6df47941d2d3'	System	22 Nov 2020 01:05:16
User entered '21 Nov 2020 18:05'	System	22 Nov 2020 01:05:16

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 4'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642'	System	22 Nov 2020 19:15:44
User entered 'None (0)'	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:18', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642'	System	22 Nov 2020 19:15:44
User entered 'None (0)'	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:21', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642'	System	22 Nov 2020 19:15:44
User entered 'None (0)'	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:24', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642'	System	22 Nov 2020 19:15:44
User entered 'None (0)'	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:26', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642'	System	22 Nov 2020 19:15:44
User entered 'None (0)'	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:29', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642'	System	22 Nov 2020 19:15:44
User entered 'None (0)'	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:35', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642'	System	22 Nov 2020 19:15:44
User entered 'No (N)'	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-22T12:15:38', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '142ab9c7-6276-4328-8939-76932ff3b642'	System	22 Nov 2020 19:15:44
User entered '22 Nov 2020 12:15'	System	22 Nov 2020 19:15:44

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 5'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:45', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0'	System	23 Nov 2020 19:36:19
User entered 'None (0)'	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:35:59', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0'	System	23 Nov 2020 19:36:19
User entered 'None (0)'	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:02', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0'	System	23 Nov 2020 19:36:19
User entered 'None (0)'	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:05', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0'	System	23 Nov 2020 19:36:19
User entered 'None (0)'	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:08', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0'	System	23 Nov 2020 19:36:19
User entered 'None (0)'	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:10', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0'	System	23 Nov 2020 19:36:19
User entered 'None (0)'	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:12', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0'	System	23 Nov 2020 19:36:19
User entered 'No (N)'	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-23T12:36:15', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: 'd3f79a4e-97fe-42de-b9de-83d1a8ef96b0'	System	23 Nov 2020 19:36:19
User entered '23 Nov 2020 12:36'	System	23 Nov 2020 19:36:19

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 6'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:22', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8'	System	25 Nov 2020 05:01:04
User entered 'None (0)'	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:35', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8'	System	25 Nov 2020 05:01:04
User entered 'None (0)'	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:37', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8'	System	25 Nov 2020 05:01:04
User entered 'None (0)'	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:40', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8'	System	25 Nov 2020 05:01:04
User entered 'None (0)'	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:43', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8'	System	25 Nov 2020 05:01:04
User entered 'None (0)'	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:47', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8'	System	25 Nov 2020 05:01:04
User entered 'None (0)'	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

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 (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:00:56', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8'	System	25 Nov 2020 05:01:04
User entered 'No (N)'	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F8D7A6C8-B515-420C-8DDF-D372DEC14EC8)', Time: '2020-11-24T22:01:00', User OID: 'PatientReportedOutcome (US3282113)', ODM File OID: '829ced9e-3170-414b-886e-36d31bea69b8'	System	25 Nov 2020 05:01:04
User entered '24 Nov 2020 22:01'	System	25 Nov 2020 05:01:04

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Nov 2020 19:50:23
User entered 'Day 7'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Nov 2020 12:00'	System	19 Nov 2020 19:50:23

US3282113

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:54:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Nov 2020 11:59'	System	19 Nov 2020 19:50:23

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 13:02:29

US3282113

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:54:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:02:29
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 13:02:29

US3282113

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:54:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:50
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	28 Oct 2020 14:23:56

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
Reviewed for Safety.	(b) (4), (b) (6)	28 Oct 2020 20:22:59
User entered 'USA-US201-2020-mRNA-1273-P301000001'	System	28 Oct 2020 20:22:53
User entered 'New'	(b) (4), (b) (6)	28 Oct 2020 20:22:53

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 15:40:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	04 Nov 2020 15:40:30
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4)	04 Nov 2020 15:25:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	04 Nov 2020 15:25:29
Data point term sent to Coder	System	04 Nov 2020 15:23:51
Coding entries removed.	Jessica Shaw (b) (4)	04 Nov 2020 15:23:04
User entered 'coronary artery disease' reason for change: New Information	Jessica Shaw (b) (4)	04 Nov 2020 15:23:04
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery occlusion, LLT: Coronary artery occlusion - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 18:03:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	29 Oct 2020 18:03:58
Data point term sent to Coder	System	28 Oct 2020 14:31:16
User entered 'Blocked Coronary Artery'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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). User entered empty.	(b) (4), (b) (6) System	04 Nov 2020 14:29:27 28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Grade 4 (Grade 4)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '1'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User closed query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:27:59
Query 'PV Query: Please provide the hospital discharge date when available' answered with 'initial discharge date=25Oct2020. Pt plans to be readmitted, and will update us once discharged.' (Site from Safety).	Jessica Shaw (b) (4)	04 Nov 2020 14:51:38
User opened query 'PV Query: Please provide the hospital discharge date when available' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 14:23:48
User entered '25 Oct 2020'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered 'None (NONE)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '1'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered '1'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
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)	05 Nov 2020 14:28:07
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 "'coronary artery disease" not expected to resolve, but procedure of coronary artery bypass graft will be performed for this condition.' (Site from Safety).	Jessica Shaw (b) (4)	04 Nov 2020 21:59:11
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)	04 Nov 2020 14:26:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User closed 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)	24 Nov 2020 16:30:42
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:30:35
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:30:27
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'records sent via email.' (Site from Safety).	Jessica Shaw (b) (4)	23 Nov 2020 22:36:24
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'laboratory and diagnostic test results added to narrative.' (Site from Safety).	Jessica Shaw (b) (4)	23 Nov 2020 19:37:02

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE STAFF TO INFORM OF RECENT HOSPITALIZATION. THE SUBJECT EXPERIENCED CHEST PAIN ON 23OCT2020. THE SUBJECT PRESENTED TO HOSPITAL WHERE STRESS TEST IDENTIFIED BLOCKED CORONARY ARTERY. THE SUBJECT WAS HOSPITALIZED UNTIL 25OCT2020. CONCOMITANT MEDICATIONS WERE STARTED AND A CORONARY BYPASS SURGERY HAS BEEN SCHEDULED FOR 02NOV2020. THE SUBJECT IS SCHEDULED TO RECEIVE DOSE 2 OF STUDY INTERVENTION ON 20NOV2020. EKG ON 30OCT2020 REVEALED SINUS BRADYCARDIA, SEPTAL INFARCT, NONSPECIFIC ST AND T WAVE ABNORMALITY. CT CORONARY ANGIOGRAPHY ON 23OCT2020 REVEALED SEVERE 100% OCCLUSION OF THE MID LAD AT THE BIFURCATION OF THE FIRST DIAGONAL ARTERY, MODERATE STENOSIS OF THE PROXIMAL RCA, INCOMPLETELY EVALUATED CYSTIC LESION WITHIN LEFT KIDNEY. Cardiac catheterization on 27Oct2020 revealed CTO of LAD with collaterals from RCA and flow visualized in LAD on RCC injection, non dominant small LCX, mild RCA disease.' reason for change: Data Entry Error DataPoint Un-verified.	Jessica Shaw (b) (4) [REDACTED]	23 Nov 2020 19:36:00
	Jessica Shaw (b) (4) [REDACTED]	23 Nov 2020 19:19:35

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED SITE STAFF TO INFORM OF RECENT HOSPITALIZATION. THE SUBJECT EXPERIENCED CHEST PAIN ON 23OCT2020. THE SUBJECT PRESENTED TO HOSPITAL WHERE STRESS TEST IDENTIFIED BLOCKED CORONARY ARTERY. THE SUBJECT WAS HOSPITALIZED UNTIL 25OCT2020. CONCOMITANT MEDICATIONS WERE STARTED AND A CORONARY BYPASS SURGERY HAS BEEN SCHEDULED FOR 02NOV2020. THE SUBJECT IS SCHEDULED TO RECEIVE DOSE 2 OF STUDY INTERVENTION ON 20NOV2020. EKG on 30Oct2020 revealed sinus bradycardia, septal infarct, nonspecific ST and T wave abnormality. CT coronary angiography on 23Oct2020 revealed severe 100% occlusion of the mid LAD at the bifurcation of the first diagonal artery, moderate stenosis of the proximal RCA, incompletely evaluated cystic lesion within left kidney.' reason for change: Data Entry Error	Jessica Shaw (b) (4)	23 Nov 2020 19:19:35
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Novel Coronavirus (COVID-19) Antigen test done via swab on 30Oct2020. Result=negative.' (Site from Safety).	Jessica Shaw (b) (4)	23 Nov 2020 19:01:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:23:45
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)	13 Nov 2020 19:23:39
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:12

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:28:20
User closed 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)	05 Nov 2020 14:28:16
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 14:28:12
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'pt with ongoing medical history item of hyperlipidemia' (Site from Safety).	Jessica Shaw (b) (4)	04 Nov 2020 14:53:39
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'will update once records are received' (Site from Safety).	Jessica Shaw (b) (4)	04 Nov 2020 14:52:36
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'will update once records are received' (Site from Safety).	Jessica Shaw (b) (4)	04 Nov 2020 14:52:09
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 14:27:34
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)	04 Nov 2020 14:25:51
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 14:25:18

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 14:24:40
User entered 'Subject contacted site staff to inform of Jessica Shaw recent hospitalization. The subject experienced chest pain on 23Oct2020. The subject presented to hospital where stress test identified blocked coronary artery. The subject was hospitalized until 25Oct2020. Concomitant medications were started and a coronary bypass surgery has been scheduled for 02Nov2020. The subject is scheduled to receive dose 2 of study intervention on 20Nov2020.'	(b) (4)	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:54:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Oct 2020 14:30:38

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:52:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 00:52:30
Data point term sent to Coder	System	06 Nov 2020 00:52:05
User entered 'congestive heart failure'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:54:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 00:51:30

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:15
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:04:54
User entered 'USA-US201-2020-mRNA-1273-P301000001'	(b) (4), (b) (6)	17 Nov 2020 19:04:50

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary thromboembolism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:50:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Nov 2020 18:50:46
Data point term sent to Coder	System	16 Nov 2020 18:50:27
User entered 'pulmonary thromboembolism'	Jessica Shaw (b) (4) [REDACTED] [REDACTED]	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:18
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:20
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:21
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:22
User entered '6 Nov 2020'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:24
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:26
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:28
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:29
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:43
User entered 'Grade 4 (Grade 4)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:44
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:16:46
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:05
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:06
User entered '1'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:09
User entered '6 Nov 2020'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:10
User entered '10 Nov 2020'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:14
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:17
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:18
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:20
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:21
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:22
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:24
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:25
User entered 'None (NONE)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:27
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'According to subject source the subject was treated with IV heparin while hospitalized and then was switched to Eliquis (Apixaban) after being discharged. Please update the concomitant medication logs accordingly. Thanks.' answered with 'added to conmed pg' (Site from CRA).	Jessica Shaw (b) (4)	19 Nov 2020 00:10:43
User opened query 'According to subject source the subject was treated with IV heparin while hospitalized and then was switched to Eliquis (Apixaban) after being discharged. Please update the concomitant medication logs accordingly. Thanks.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:21:50
Query 'According to subject source the subject was treated with IV heparin while hospitalized and then was switched to Eliquis after being discharged. Please update the concomitant medication logs accordingly. Thanks. ' canceled (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:21:38
User opened query 'According to subject source the subject was treated with IV heparin while hospitalized and then was switched to Eliquis after being discharged. Please update the concomitant medication logs accordingly. Thanks. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:20:53
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:29
User entered 'I'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:33
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:38
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:17:40
User entered 'Pt was discharged from hospital on 06Nov2020 following hospitalization for CABG procedure. Later that evening, pt experienced shortness of breath and was seen in emergency department. Pt was diagnosed with pulmonary thromboembolism and was admitted to hospital. Pt was started on IV heparin, then transitioned to Eliquis. Pt was discharged to home on 10Nov2020.'	Jessica Shaw (b) (4)	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:54:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 18:50:09

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:01:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:01:51
Data point term sent to Coder	System	16 Nov 2020 20:31:13
User entered 'post coronary artery bypass graft pain'	Jessica Shaw (b) (4) (b) (4) (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Nov 2020'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jessica Shaw (b) (4) [REDACTED] [REDACTED]	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:54:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Nov 2020 20:30:34

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Musculoskeletal chest pain, LLT: Musculoskeletal chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:16:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:16:06
Data point term sent to Coder	System	23 Nov 2020 18:58:34
User entered 'worsening of midsternal chest pain'	Jessica Shaw (b) (4) (b) (4) (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[None](#)

Audit	User	Time (GMT)
User entered '1'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessica Shaw (b) (4) [REDACTED] [REDACTED]	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:54:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 18:58:29

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal neoplasms, PT: Renal cyst, LLT: Cyst of kidney - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:59:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:59:37
Data point term sent to Coder	System	23 Nov 2020 19:21:11
User entered 'cystic lesion within left kidney'	Jessica Shaw (b) (4) (b) (4) (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:20:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 19:20:54
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw (b) (4) [REDACTED]	23 Nov 2020 19:20:54
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 19:20:49
User entered empty.	Jessica Shaw (b) (4) [REDACTED]	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[None](#)

Audit	User	Time (GMT)
User entered '1'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 19:20:49

US3282113

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 10:54:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 19:20:49

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:54:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:37:42
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:15:30

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:18:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:18:38
Data point term sent to Coder	System	23 Oct 2020 15:17:17
User entered 'atorvastatin'	Jessica Shaw (b) (4) (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'hyperlipidemia'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '20'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'mg (mg)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'un UNK 2017'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jessica Shaw (b) (4)	06 Nov 2020 00:37:38
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw (b) (4)	06 Nov 2020 00:37:38
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Jessica Shaw (b) (4)	06 Nov 2020 00:37:38
User entered '23 Oct 2020' reason for change: Data Entry Error	Jessica Shaw (b) (4)	06 Nov 2020 00:37:38
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:16:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:18:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:18:37
Data point term sent to Coder	System	23 Oct 2020 15:17:20
User entered 'levothyroxine'	Jessica Shaw (b) (4) (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'hypothyroidism'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '85'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'ug (ug)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'un UNK 2017'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw (b) (4)	04 Nov 2020 15:35:23
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '23 Oct 2020' reason for change: Data Entry Error	Jessica Shaw (b) (4)	04 Nov 2020 15:35:23
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:16:59

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 15:19:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	23 Oct 2020 15:19:29
Data point term sent to Coder	System	23 Oct 2020 15:18:21
User entered 'tamsulosin'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'benign prostatic hyperplasia'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '.4'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'mg (mg)'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'twice daily (BID)'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'un Sep 2018'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 15:17:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: IPRATROPIUM BROMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:23:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 15:23:42
Data point term sent to Coder	System	23 Oct 2020 15:18:22
User entered 'ipratropium bromide'	Jessica Shaw (b) (4) (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'seasonal allergies'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '2'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Other (OTHER)'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'sprays'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'as needed (PRN)'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'un UNK 2015'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 15:18:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:43:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:48:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:48:31
Data point term sent to Coder Coding entries removed.	System Jessica Shaw (b) (4)	06 Nov 2020 00:48:01 06 Nov 2020 00:47:15
Query 'Source indicates given for symptoms of CHF, Please review and amend as needed' answered with 'corrected. added AE of CHF.' (Site from CRA).	Jessica Shaw (b) (4)	06 Nov 2020 00:47:07
User opened query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:39:23
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:04:26
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 18:04:26
Data point term sent to Coder User entered 'losartan'	System Jessica Shaw (b) (4)	28 Oct 2020 14:44:33 28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:43:09
DataPoint Un-verified.	Jessica Shaw (b) (4)	06 Nov 2020 00:47:15
User entered 'congestive heart failure' reason for change: Data Entry Error	Jessica Shaw (b) (4)	06 Nov 2020 00:47:15
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'blocked coronary artery'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '25'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'mg (mg)'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '24 Oct 2020'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	dylan owen (b) (4)	19 Nov 2020 23:20:12
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 23:20:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	dylan owen (b) (4)	19 Nov 2020 23:20:12
	(b) (4)	
User entered '6 Nov 2020' reason for change: Data Entry Error	dylan owen (b) (4)	19 Nov 2020 23:20:12
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 14:43:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:48:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:48:31
Data point term sent to Coder	System	06 Nov 2020 00:48:01
Coding entries removed.	Jessica Shaw (b) (4)	06 Nov 2020 00:47:34
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:04:44
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 18:04:44
Data point term sent to Coder	System	28 Oct 2020 14:44:35
User entered 'metoprolol'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:43:17
User closed query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:43:15
DataPoint Un-verified.	Jessica Shaw (b) (4)	06 Nov 2020 00:47:34
User entered 'congestive heart failure' reason for change: Data Entry Error	Jessica Shaw (b) (4)	06 Nov 2020 00:47:34
Query 'Source indicates given for symptoms of CHF, Please review and amend as needed' answered with 'corrected. Added AE of CHF.' (Site from CRA).	Jessica Shaw (b) (4)	06 Nov 2020 00:47:26
User opened query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:39:38
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'blocked coronary artery'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '25'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'mg (mg)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '24 Oct 2020'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 14:44:12

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:51:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 00:51:24
Data point term sent to Coder	System	06 Nov 2020 00:50:04
Coding entries removed.	Jessica Shaw (b) (4)	06 Nov 2020 00:49:18
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:46:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:46:37
Data point term sent to Coder	System	28 Oct 2020 14:45:36
User entered 'atorvastatin'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:43:26
User closed query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:43:24
DataPoint Un-verified.	Jessica Shaw (b) (4)	06 Nov 2020 00:49:18
User entered 'coronary artery disease' reason for change: Data Entry Error	Jessica Shaw (b) (4)	06 Nov 2020 00:49:18
Query 'Source indicates given for symptoms of CHF, Please review and amend as needed' answered with 'atorvastatin not given specifically for CHF. dosage was changed during hospital stay, for coronary artery disease diagnosis.' (Site from CRA).	Jessica Shaw (b) (4)	06 Nov 2020 00:49:11
User opened query 'Source indicates given for symptoms of CHF, Please review and amend as needed' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:40:15
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'blocked coronary artery'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '40'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'mg (mg)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '24 Oct 2020'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 14:44:48

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 15:52:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 15:52:28
Data point term sent to Coder	System	04 Nov 2020 15:36:13
User entered 'levothyroxine'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'hypothyroidism'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '88'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'ug (ug)'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'once daily (QD)'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '24 Oct 2020'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered '0'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered empty.	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:38:19
User entered 'No (N)'	Jessica Shaw (b) (4)	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 15:35:56

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 12:14:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 12:14:59
Data point term sent to Coder	System	19 Nov 2020 00:08:30
User entered 'heparin'	Jessica Shaw (b) (4) (b) (4) (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'pulmonary thromboembolism'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'unk'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'unknown'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'unknown (UNKNOWN)'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un Nov 2020'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Nov 2020'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:08:05

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:59:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:59:53
Data point term sent to Coder	System	19 Nov 2020 00:09:30
User entered 'apixaban'	Jessica Shaw (b) (4) (b) (4) (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'pulmonary thromboembolism'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Nov 2020'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 00:09:06

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:14:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:14:52
Data point term sent to Coder	System	19 Nov 2020 00:10:31
User entered 'aspirin'	Jessica Shaw (b) (4) (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'anti-coagulation post CABG'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered 'un Nov 2020'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Nov 2020 00:09:42

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:02:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:02:57
Data point term sent to Coder	System	19 Nov 2020 00:10:34
User entered 'oxycodone'	Jessica Shaw (b) (4) (b) (4) (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'post CABG pain'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '5'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un Nov 2020'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Jessica Shaw (b) (4)	23 Nov 2020 18:59:41
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Nov 2020' reason for change: Data Entry Error	Jessica Shaw (b) (4)	23 Nov 2020 18:59:41
User entered empty.	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 00:10:24

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:37:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:37:51
Data point term sent to Coder	System	19 Nov 2020 23:23:24
Data point term sent to Coder	System	19 Nov 2020 23:22:24
User entered 'Pneumovax'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'pneumonia phophylaxis'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'injection'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:22:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 23:22:45
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:45
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 23:22:21
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

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

Audit	User	Time (GMT)
User entered '10 Nov 2020'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	dylan owen (b) (4) (b) (4)	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 23:22:21

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:23:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:23:07
Data point term sent to Coder	System	23 Nov 2020 19:26:20
User entered 'sodium chloride flush'	Jessica Shaw (b) (4) (b) (4) (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'coronary artery disease'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:26:09

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:23:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 04:23:08
Data point term sent to Coder	System	23 Nov 2020 19:29:24
User entered 'sodium chloride 0.9% bolus'	Jessica Shaw (b) (4) (b) (4) (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'coronary artery disease'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '333.55'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Oct 2020'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Shaw (b) (4)	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:54:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 19:29:08

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:54:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Shaw (b) (4)	04 Nov 2020 19:37:07

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Nov 2020'	Jessica Shaw (b) (4)	04 Nov 2020 19:37:21

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'coronary artery bypass graft'	Jessica Shaw (b) (4)	04 Nov 2020 19:37:21

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Jessica Shaw (b) (4)	04 Nov 2020 19:37:21

US3282113

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:54:31

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Shaw (b) (4)	04 Nov 2020 19:37:21

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Serious](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:54:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered '28/Oct/2020 16:23'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:54:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:54:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User entered '05/Nov/2020 14:28'	System	05 Nov 2020 14:28:38

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:54:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	17 Nov 2020 19:05:12
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 14:28:38

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:54:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '17/Nov/2020 19:05'	System	17 Nov 2020 19:05:23

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 10:54:31

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)	17 Nov 2020 19:05:23

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'USA-US201-2020-MRNA-1273-P301000001'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Yes (Y)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'No (N)'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Shane'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Christensen'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '6360 South 3000 East'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'Salt Lake City'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered 'UT'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 20:23:17
User entered '84121'	System	28 Oct 2020 20:22:53

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:36:30
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 14:28:28
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
User entered 'US'	(b) (4) System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 10:54:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 16:31:36
User entered '3'	System	17 Nov 2020 19:05:23
Signature has been broken.	System	05 Nov 2020 14:28:38
User entered '2'	System	05 Nov 2020 14:28:38
User signature succeeded.	Shane Christensen (b) (4)	28 Oct 2020 21:42:12
	(b) (4)	
User entered '1'	System	28 Oct 2020 20:23:25

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:54:31

[Date of submission \(Pre-filled from custom function\)](#)

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

US3282113

Folder: SAE USA-US201-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 10:54:31

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 16:31:36