

US3412328 (Prod: New Horizons Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:23:00

All time stamps listed in this document are displayed in GMT

US3412328

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:00

[Participant ID](#)

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

US3412328

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	64
Age Units	YEARS
Age (Derived)	64
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

Date of Informed Consent (<i>dd MMM yyyy</i>)	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☐
	Amendment 3 ☒
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:23:00

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:00

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

Condition	ALLERGIC RHINITIS - SEASONAL
Start date (dd MMM yyyy)	UN UNK 1981
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

Condition	OSTEOARTHRITS - BILATERAL KNEES, HAND, FOOT, BACK
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

Condition	GASTROESOPHOGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

Condition	AFIBRILLATION - (ATRIAL FIBRILLATION) SYMPTON FREE SINCE ABLATION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

Condition	CARDIAC ABLATION
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	26 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:15 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 14:15
Height (<i>xxx.x</i>)	179.6 cm
Weight (<i>xxx.x</i>)	92.2 kg
BMI (<i>xxx.x</i>)	28.58369 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:00

Date of assessment (*dd MMM yyyy*) 26 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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

HIGH RISK PATIENT, SHOPS,
VISITS FAMILY AND FRIENDS,
GOES TO SOCIAL GATHERINGS

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 09:23:00

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 09:23:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:00

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 108845

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:00

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 14:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	15:46 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 15:46
Temperature (xxx.x)	97.8 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 15:10 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 15:10

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

26 AUG 2020

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

14:45 (24 HR)

Collection date and time (derived)

26 AUG 2020 14:45

US3412328

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:00

Collection date (<i>dd MMM yyyy</i>)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:49	26 AUG 2020 14:49
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 15:50

PC Open Date & Time

26 AUG 2020 15:30

PC Close Date & Time

26 AUG 2020 18:00

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

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

26 AUG 2020 18:55

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 16:52

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:00

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

97.5 °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

28 AUG 2020 20:59

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:00

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**

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 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:00

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

97.5 °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

30 AUG 2020 18:10

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:00

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

31 AUG 2020 21:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:00

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

01 SEP 2020 21:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

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

26 AUG 2020 15:50

PC Open Date & Time

26 AUG 2020 15:30

PC Close Date & Time

26 AUG 2020 18:00

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 AUG 2020 18:55

PC Close Date & Time

27 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:00

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

27 AUG 2020 16:53

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:00

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

28 AUG 2020 21:00

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:00

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 ☐

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

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:00

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

30 AUG 2020 18:10

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:00

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

31 AUG 2020 21:07

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 21:16

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 15:51
PC Open Date & Time	26 AUG 2020 15:30
PC Close Date & Time	26 AUG 2020 18:00

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

26 AUG 2020 18:55

PC Close Date & Time

27 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

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 ☒

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

Yes ☐	
PC Time stamp	27 AUG 2020 16:53
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

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 ☒

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

Yes ☐	
PC Time stamp	28 AUG 2020 21:00
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:00

		Yes ☐
PC Time stamp		
PC Open Date & Time		29 AUG 2020 12:00
PC Close Date & Time		30 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

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 ☒

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

Yes ☐	
PC Time stamp	30 AUG 2020 18:11
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

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 ☒

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

Yes ☐	
PC Time stamp	31 AUG 2020 21:08
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

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 ☒

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

Yes ☐	
PC Time stamp	01 SEP 2020 21:17
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time	02 SEP 2020 12:00
---------------------	-------------------

PC Close Date & Time	03 SEP 2020 11:59
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PC Time stamp	03 SEP 2020 11:01
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US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of **CHILLS** you
are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

PC Time stamp

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of **CHILLS** you
are experiencing

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

PC Time stamp

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	03 SEP 2020 11:01
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412328

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

Was Contact Attempted?

Yes ☒

No ☐

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

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412328

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412328

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412328

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412328

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

Was Contact Attempted?

Yes ☒

No ☐

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

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412328

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412328

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	06 OCT 2020
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 15:35
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3412328

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	06 OCT 2020
Collection time (<i>00:00-23:59</i>)	16:00 (24 HR)
Collection date and time (derived)	06 OCT 2020 16:00

US3412328

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:00

Collection date (dd MMM yyyy)			06 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:15	06 OCT 2020 16:15
Nasopharyngeal Swab 2	No		

US3412328

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412328

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

Was Contact Attempted?

Yes ☒

No ☐

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

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412328

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412328

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412328

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412328

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

Was Contact Attempted?

Yes ☒

No ☐

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

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412328

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412328

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	3 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3412328

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	3 NOV 2020
Collection time (<i>00:00-23:59</i>)	09:07 (24 HR)
Collection date and time (derived)	3 NOV 2020 09:07

US3412328

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

DAY 341

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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°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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

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24 MAY 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

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21 JUN 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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12 JUL 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

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15 JUL 2022 00:01

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19 JUL 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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26 JUL 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

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29 JUL 2022 00:01

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02 AUG 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

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09 AUG 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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16 AUG 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

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13 SEP 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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 SEP 2022 00:01

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20 SEP 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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°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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3412328

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412328

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:23:00

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412328

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:00

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

AEID	
Adverse event	CHEST PAIN (ETIOLOGY - UNDETERMINED)
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)	05 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	01 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	
v6.020 DTW (1102)	
310 of 1456	

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

AEID	USA-US061-2020-MRNA-1273-P30 1000010
Adverse event	ATYPICAL 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)	17 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	18 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	17 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	18 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	312 of 1456

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

DUE TO CHEST PRESSURE
SUBJECT WAS ADVISED TO GO
TO ER FOR EVALUATION. PER
ER DOCTOR SUBJECT WAS
ADMITTED OVERNIGHT FOR
OBSERVATION. SUBJECT'S
TESTING HAS ALL BEEN
NEGATIVE FOR ANY CARDIAC
ISSUES. SUBJECT HAS NO
OTHER COMPLAINTS, NO
FEVER, NO SHORTNESS OF
BREATH, SUBJECT HAD AN
ECHOCARDIOGRAM BEFORE
DISCHARGE.

SITE ATTEMPTED TO OBTAIN
MEDICAL RECORDS.
HOWEVER, SUBJECT REFUSED
RELEASE OF ANY MEDICAL
RECORDS FROM HER STAY.
SITE WAS ONLY ABLE TO
CONFIRM SAE DIAGNOSIS DUE
TO ER DOCTOR CONFIRMING
SUBJECT WAS ADMITTED TO
THE HOSPITAL OVERNIGHT
FOR OBSERVATION. SUBJECT
HAS SINCE RESOLVED ALL
ISSUES AND SITE IS UNABLE
TO DO ANY FURTHER FOLLOW
UP WITHOUT MEDICAL
RECORDS.

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

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:00

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

Yes ☒

No ☐

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

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

Name of Medication	FLONASE, OTC (FLUTICASONE)
Prophylaxis	Yes ☐ No ☒
Indication	ALLERGIC RHINITIS - SEASONAL
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☒ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

Name of Medication	NORETHINDRONE ACETAT-ETHINYL
Prophylaxis	Yes ☐ No ☒
Indication	.OSTEOPENIA
Dose per administration	0.5/2.5
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	MCG
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

Name of Medication CREAM FOR PAIN - BACLOFEN,
DICLOFENAC, GABAPENTIN,
LIDOCAINE -

Prophylaxis Yes ☐
No ☒

Indication PAIN FOR FOOT

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify TOPICAL CREAM - 1G

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

Name of Medication	CALCIUM
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH
Dose per administration	1200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

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

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

Name of Medication	PEPCID
Prophylaxis	Yes ☐ No ☒
Indication	GERD
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		29 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3412328

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:23:00

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3412328

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:23:00

Date of dosing discontinuation (dd MMM yyyy)

06 OCT 2020

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

SUBJECT HAD CHEST PAIN
BETWEEN VISIT 1 AND VISIT 2.
SUBJECT WAS MEDICALLY
CLEARED OF SYMPTOMS BY
VISIT 2, BUT HAS DECIDED
THAT THEY DID NOT WANT
THE SECOND DOSAGE.
SUBJECT WILL CONTINUE IN
STUDY.

US3412328

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:23:00

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 ☐

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

SAEID	USA-US061-2020-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:00

SAEID	USA-US061-2020-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	12/NOV/2020 01:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412328 (Prod: New Horizons Clinical Research)

US3412328

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:00

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3412328'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 17:44:45

US3412328

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:30:52

US3412328

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 17:44:46

US3412328

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Aug 2020 19:30:52

US3412328

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	26 Aug 2020 19:30:52

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered (b) (6) 1956'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 17:44:47

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[Age](#)

Audit	User	Time (GMT)
User entered '64'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '64'	System	26 Aug 2020 19:32:18

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

White

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

Unknown

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:00

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	26 Aug 2020 19:31:27

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 19:32:18

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	26 Aug 2020 19:32:18

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '2020'	System	26 Aug 2020 19:32:18

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	26 Aug 2020 19:32:18

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:32:18

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:32:18

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:32:18

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:32:18

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	26 Aug 2020 17:44:46

US3412328

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:00

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 19:33:06

US3412328

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:33:06

US3412328

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:34:10

US3412328

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

[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 allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:36:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:36:52
Data point term sent to Coder	System	03 Sep 2020 20:35:19
User entered 'allergic rhinitis - seasonal'	Jacob sekinger (b) (4)	03 Sep 2020 20:34:41

US3412328

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 1981'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:34:41

US3412328

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:34:41

US3412328

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:34:41

US3412328

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:34:41

US3412328

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:34:41

US3412328

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Jan 1981'	System	03 Sep 2020 20:34:41

US3412328

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '1981'	System	03 Sep 2020 20:34:41

US3412328

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:34:41

US3412328

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:34:41

US3412328

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

[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: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:36:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 20:36:52
Data point term sent to Coder	System	03 Sep 2020 20:35:20
User entered 'sleep apnea'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:04

US3412328

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:04

US3412328

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:04

US3412328

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:04

US3412328

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:04

US3412328

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:04

US3412328

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	03 Sep 2020 20:35:04

US3412328

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '2018'	System	03 Sep 2020 20:35:04

US3412328

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:35:04

US3412328

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:35:04

US3412328

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalised osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:59:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:59:55
Data point term sent to Coder	System	03 Nov 2020 15:27:57
Coding entries removed.	Melissa Fuson (b) (4)	03 Nov 2020 15:27:07
User entered 'OSTEOARTHRITS - BILATERAL KNEES, HAND, FOOT, BACK' reason for change:	Melissa Fuson (b) (4)	03 Nov 2020 15:27:07
Data Entry Error	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 07:53:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 07:53:35
Data point term sent to Coder	System	03 Sep 2020 20:36:23
User entered 'osteoarthrits - knees, hand, foot, back'	Jacob sekinger (b) (4)	03 Sep 2020 20:35:39
	(b) (4)	

US3412328

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:39

US3412328

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:39

US3412328

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:39

US3412328

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:39

US3412328

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:35:39

US3412328

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	03 Sep 2020 20:35:39

US3412328

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '2010'	System	03 Sep 2020 20:35:39

US3412328

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:35:39

US3412328

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:35:39

US3412328

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:37:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 20:37:40
Data point term sent to Coder	System	03 Sep 2020 20:36:23
User entered 'osteopenia'	Jacob sekinger (b) (4)	03 Sep 2020 20:36:10
	(b) (4)	

US3412328

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:36:10

US3412328

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:36:10

US3412328

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:36:10

US3412328

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:36:10

US3412328

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:36:10

US3412328

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	03 Sep 2020 20:36:10

US3412328

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '2015'	System	03 Sep 2020 20:36:10

US3412328

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:36:10

US3412328

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:36:10

US3412328

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 23:57:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	08 Oct 2020 23:57:35
Data point term sent to Coder	System	08 Oct 2020 18:42:37
User entered 'Post menopausal'	Steven Anderson (b) (4)	08 Oct 2020 18:42:36
	(b) (4)	

US3412328

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	Steven Anderson (b) (4)	08 Oct 2020 18:42:36
	(b) (4)	

US3412328

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 18:42:36

US3412328

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

[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	08 Oct 2020 18:42:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 18:42:44
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).	System	08 Oct 2020 18:42:36
User entered 'No (N)'	Steven Anderson (b) (4)	08 Oct 2020 18:42:36

US3412328

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:42:36
	(b) (4)	

US3412328

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4)	08 Oct 2020 18:42:36
	(b) (4)	

US3412328

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	08 Oct 2020 18:42:36

US3412328

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '2004'	System	08 Oct 2020 18:42:36

US3412328

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:42:36

US3412328

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:42:36

US3412328

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 14:40:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 14:40:22
Data point term sent to Coder	System	03 Nov 2020 14:38:47
User entered 'Gastroesophogeal reflux disease'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:38:36

US3412328

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:38:36

US3412328

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:38:36

US3412328

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:38:36

US3412328

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:38:36

US3412328

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:38:36

US3412328

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	03 Nov 2020 14:38:36

US3412328

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '2016'	System	03 Nov 2020 14:38:36

US3412328

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 14:38:36

US3412328

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 14:38:36

US3412328

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 23:01:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 23:01:23
Data point term sent to Coder	System	03 Nov 2020 15:31:03
User entered 'AFIBRILLATION - (ATRIAL FIBRILLATION) SYMPTON FREE SINCE ABLATION'	Melissa Fuson (b) (4)	03 Nov 2020 15:30:28

US3412328

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:30:28

US3412328

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:30:28

US3412328

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:30:28

US3412328

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:30:28

US3412328

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:30:28

US3412328

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	03 Nov 2020 15:30:28

US3412328

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '2015'	System	03 Nov 2020 15:30:28

US3412328

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	03 Nov 2020 15:30:28

US3412328

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '2016'	System	03 Nov 2020 15:30:28

US3412328

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Cardiac ablation, LLT: Cardiac ablation - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 15:33:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 15:33:20
Data point term sent to Coder	System	03 Nov 2020 15:32:04
User entered 'CARDIAC ABLATION'	Melissa Fuson (b) (4)	03 Nov 2020 15:31:36

US3412328

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:31:36

US3412328

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:31:36

US3412328

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:31:36

US3412328

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:31:36

US3412328

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:31:36

US3412328

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	03 Nov 2020 15:31:36

US3412328

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '2016'	System	03 Nov 2020 15:31:36

US3412328

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	03 Nov 2020 15:31:36

US3412328

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '2016'	System	03 Nov 2020 15:31:36

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '14:15'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 14:15'	System	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '179.6' cm	Jacob sekinger (b) (4)	03 Sep 2020 20:45:46
DataPoint set to visible.	(b) (4) System	26 Aug 2020 19:33:06

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '92.2' kg	Jacob sekinger (b) (4)	03 Sep 2020 20:45:46
DataPoint set to visible.	(b) (4) System	26 Aug 2020 19:33:06

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '28.58369'	System	03 Sep 2020 20:45:46
DataPoint set to visible.	System	26 Aug 2020 19:33:06

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	03 Sep 2020 20:45:46
DataPoint set to visible.	System	26 Aug 2020 19:33:06

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 20:45:46

US3412328

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:46:11

US3412328

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:46:11

US3412328

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:46:46

US3412328

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:46:46

US3412328

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:00

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:03:06
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'this has been updated to medical history' (Site from DM).	Steven Anderson (b) (4)	08 Oct 2020 18:43:18
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:14:50
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Jacob sekinger (b) (4)	03 Sep 2020 20:46:46

US3412328

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:46:46

US3412328

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:46:46

US3412328

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:00

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:46:46

US3412328

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:46:46

US3412328

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:00

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '1'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:46:46

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

[Specify](#)

Audit	User	Time (GMT)
User entered 'High risk patient, shops, visits family and friends, Goes to social gatherings'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '1'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:00

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:48:45

US3412328

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:33:18

US3412328

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 19:33:18

US3412328

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Aug 2020 19:33:18

US3412328

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	26 Aug 2020 19:33:18

US3412328

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 19:00:56

US3412328

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '108845'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 19:00:56

US3412328

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) 	26 Aug 2020 19:00:56

US3412328

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:33:29

US3412328

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:33:29

US3412328

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:33:29

US3412328

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:00

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:33:29

US3412328

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:00

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 19:33:29

US3412328

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4)	28 Sep 2020 18:20:31
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 08:05:26
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:05:25

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:00

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:00

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '14:15'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 14:15'	System	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.7' C	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '70'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '14'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '100'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:00

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '15:46'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:46'	System	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '15'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '100'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '68'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	03 Sep 2020 20:51:28

US3412328

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: For Screening and Visit 1 on the same day, Physical Examination should be recorded as 'No' in Visit 1 as per CCGs to avoid duplication of data. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:42:35
Query 'Per CDM: For Screening and Visit 1 on the same day, Physical Examination should be recorded as 'No' in Visit 1 as per CCGs to avoid duplication of data. Please update accordingly.' answered with 'updated.' (Site from DM).	Jacob sekinger (b) (4)	21 Oct 2020 19:45:21
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	21 Oct 2020 19:45:04
User opened query 'Per CDM: For Screening and Visit 1 on the same day, Physical Examination should be recorded as 'No' in Visit 1 as per CCGs to avoid duplication of data. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:58:04
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	03 Sep 2020 20:52:00

US3412328

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jacob sekinger (b) (4)	21 Oct 2020 19:45:04
User entered '26 Aug 2020'	Jacob sekinger (b) (4)	03 Sep 2020 20:52:00

US3412328

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 19:34:02

US3412328

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:34:02

US3412328

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 19:34:02

US3412328

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 19:34:02

US3412328

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 19:34:02

US3412328

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '15:10'	(b) (4), (b) (6)	26 Aug 2020 19:34:02

US3412328

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:10'	System	26 Aug 2020 19:34:02

US3412328

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	26 Aug 2020 19:34:02

US3412328

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	26 Aug 2020 19:34:02

US3412328

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 19:34:02

US3412328

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:52:59

US3412328

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:52:59

US3412328

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:45'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:52:59

US3412328

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 14:45'	System	03 Sep 2020 20:52:59

US3412328

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:53:54

US3412328

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	03 Sep 2020 20:53:54

US3412328

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:53:54

US3412328

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:49'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:53:54

US3412328

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '26 Aug 2020 14:49'	System	03 Sep 2020 20:53:54

US3412328

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:53:54

US3412328

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:53:54

US3412328

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:53:54

US3412328

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:53:54

US3412328

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 17:16:43

US3412328

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:16:43

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:49:49', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'b7ca03f9-49b0-48b6-9238-6b798fa389d8'	System	26 Aug 2020 19:50:21
User entered 'Yes (Y)'	System	26 Aug 2020 19:50:21

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:05', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'b7ca03f9-49b0-48b6-9238-6b798fa389d8'	System	26 Aug 2020 19:50:21
User entered '97.8'	System	26 Aug 2020 19:50:21

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:10', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'b7ca03f9-49b0-48b6-9238-6b798fa389d8'	System	26 Aug 2020 19:50:21
User entered 'No (N)'	System	26 Aug 2020 19:50:21

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:18', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'b7ca03f9-49b0-48b6-9238-6b798fa389d8'	System	26 Aug 2020 19:50:21
User entered '26 Aug 2020 15:50'	System	26 Aug 2020 19:50:21

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:30'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:55'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 2'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:52:10', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '0bca5e2b-cf5a-4aec-b72c-8b486ae11436'	System	27 Aug 2020 20:52:29
User entered 'Yes (Y)'	System	27 Aug 2020 20:52:29

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:52:18', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '0bca5e2b-cf5a-4aec-b72c-8b486ae11436'	System	27 Aug 2020 20:52:29
User entered '98.4'	System	27 Aug 2020 20:52:29

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:52:22', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '0bca5e2b-cf5a-4aec-b72c-8b486ae11436'	System	27 Aug 2020 20:52:29
User entered 'No (N)'	System	27 Aug 2020 20:52:29

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:52:27', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '0bca5e2b-cf5a-4aec-b72c-8b486ae11436'	System	27 Aug 2020 20:52:29
User entered '27 Aug 2020 16:52'	System	27 Aug 2020 20:52:29

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 3'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T20:59:31', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '7f1cb3bf-9bb2-499f-b1ac-1239077997ca'	System	29 Aug 2020 00:59:46
User entered 'Yes (Y)'	System	29 Aug 2020 00:59:46

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T20:59:38', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '7f1cb3bf-9bb2-499f-b1ac-1239077997ca'	System	29 Aug 2020 00:59:46
User entered '97.5'	System	29 Aug 2020 00:59:46

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T20:59:41', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '7f1cb3bf-9bb2-499f-b1ac-1239077997ca'	System	29 Aug 2020 00:59:46
User entered 'No (N)'	System	29 Aug 2020 00:59:46

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T20:59:44', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '7f1cb3bf-9bb2-499f-b1ac-1239077997ca'	System	29 Aug 2020 00:59:46
User entered '28 Aug 2020 20:59'	System	29 Aug 2020 00:59:46

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 4'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 5'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:10:23', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2e788d30-3f95-4b5c-9289-b271f03e7fab'	System	30 Aug 2020 22:10:40
User entered 'Yes (Y)'	System	30 Aug 2020 22:10:40

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:10:30', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2e788d30-3f95-4b5c-9289-b271f03e7fab'	System	30 Aug 2020 22:10:40
User entered '97.5'	System	30 Aug 2020 22:10:40

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:10:33', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2e788d30-3f95-4b5c-9289-b271f03e7fab'	System	30 Aug 2020 22:10:40
User entered 'No (N)'	System	30 Aug 2020 22:10:40

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:10:37', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2e788d30-3f95-4b5c-9289-b271f03e7fab'	System	30 Aug 2020 22:10:40
User entered '30 Aug 2020 18:10'	System	30 Aug 2020 22:10:40

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 6'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:09', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a8a1413f-f397-4705-b6db-180389dcae62'	System	01 Sep 2020 01:07:29
User entered 'Yes (Y)'	System	01 Sep 2020 01:07:29

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:18', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a8a1413f-f397-4705-b6db-180389dcae62'	System	01 Sep 2020 01:07:29
User entered '97.2'	System	01 Sep 2020 01:07:29

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:21', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a8a1413f-f397-4705-b6db-180389dcae62'	System	01 Sep 2020 01:07:29
User entered 'No (N)'	System	01 Sep 2020 01:07:29

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:25', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a8a1413f-f397-4705-b6db-180389dcae62'	System	01 Sep 2020 01:07:29
User entered '31 Aug 2020 21:07'	System	01 Sep 2020 01:07:29

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 7'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:00

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:15:42', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '1ea823bd-fa76-4970-bf32-ce22a9b544a4'	System	02 Sep 2020 01:16:02
User entered 'Yes (Y)'	System	02 Sep 2020 01:16:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:15:49', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '1ea823bd-fa76-4970-bf32-ce22a9b544a4'	System	02 Sep 2020 01:16:02
User entered '97.2'	System	02 Sep 2020 01:16:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:15:52', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '1ea823bd-fa76-4970-bf32-ce22a9b544a4'	System	02 Sep 2020 01:16:02
User entered 'No (N)'	System	02 Sep 2020 01:16:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:15:57', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '1ea823bd-fa76-4970-bf32-ce22a9b544a4'	System	02 Sep 2020 01:16:02
User entered '01 Sep 2020 21:15'	System	02 Sep 2020 01:16:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:30', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '6c4a9dad-bed2-4e43-98e7-8dd79f05eb94'	System	26 Aug 2020 19:50:46
User entered 'None (1)'	System	26 Aug 2020 19:50:46

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:33', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '6c4a9dad-bed2-4e43-98e7-8dd79f05eb94'	System	26 Aug 2020 19:50:46
User entered 'No (N)'	System	26 Aug 2020 19:50:46

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:36', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '6c4a9dad-bed2-4e43-98e7-8dd79f05eb94'	System	26 Aug 2020 19:50:46
User entered 'No (N)'	System	26 Aug 2020 19:50:46

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:41', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '6c4a9dad-bed2-4e43-98e7-8dd79f05eb94'	System	26 Aug 2020 19:50:46
User entered 'None (1)'	System	26 Aug 2020 19:50:46

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:44', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '6c4a9dad-bed2-4e43-98e7-8dd79f05eb94'	System	26 Aug 2020 19:50:46
User entered '26 Aug 2020 15:50'	System	26 Aug 2020 19:50:46

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:30'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:55'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 2'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:52:36', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'fe006d84-1cf7-4175-be96-e6a5c972d409'	System	27 Aug 2020 20:53:03
User entered 'None (1)'	System	27 Aug 2020 20:53:03

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:52:39', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'fe006d84-1cf7-4175-be96-e6a5c972d409'	System	27 Aug 2020 20:53:03
User entered 'No (N)'	System	27 Aug 2020 20:53:03

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:52:47', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'fe006d84-1cf7-4175-be96-e6a5c972d409'	System	27 Aug 2020 20:53:03
User entered 'No (N)'	System	27 Aug 2020 20:53:03

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:52:57', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'fe006d84-1cf7-4175-be96-e6a5c972d409'	System	27 Aug 2020 20:53:03
User entered 'None (1)'	System	27 Aug 2020 20:53:03

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:53:00', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'fe006d84-1cf7-4175-be96-e6a5c972d409'	System	27 Aug 2020 20:53:03
User entered '27 Aug 2020 16:53'	System	27 Aug 2020 20:53:03

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 3'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T20:59:50', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '5d6b747d-b27e-4bee-9517-48d253c67127'	System	29 Aug 2020 01:00:11
User entered 'None (1)'	System	29 Aug 2020 01:00:11

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T20:59:53', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '5d6b747d-b27e-4bee-9517-48d253c67127'	System	29 Aug 2020 01:00:11
User entered 'No (N)'	System	29 Aug 2020 01:00:11

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T20:59:56', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '5d6b747d-b27e-4bee-9517-48d253c67127'	System	29 Aug 2020 01:00:11
User entered 'No (N)'	System	29 Aug 2020 01:00:11

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T21:00:00', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '5d6b747d-b27e-4bee-9517-48d253c67127'	System	29 Aug 2020 01:00:11
User entered 'None (1)'	System	29 Aug 2020 01:00:11

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T21:00:04', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '5d6b747d-b27e-4bee-9517-48d253c67127'	System	29 Aug 2020 01:00:11
User entered '28 Aug 2020 21:00'	System	29 Aug 2020 01:00:11

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 4'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 5'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:10:43', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '8d63dec7-b5f5-430e-b3f1-283dc98f9a10'	System	30 Aug 2020 22:11:00
User entered 'None (1)'	System	30 Aug 2020 22:11:00

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:10:46', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '8d63dec7-b5f5-430e-b3f1-283dc98f9a10'	System	30 Aug 2020 22:11:00
User entered 'No (N)'	System	30 Aug 2020 22:11:00

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:10:49', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '8d63dec7-b5f5-430e-b3f1-283dc98f9a10'	System	30 Aug 2020 22:11:00
User entered 'No (N)'	System	30 Aug 2020 22:11:00

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:10:52', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '8d63dec7-b5f5-430e-b3f1-283dc98f9a10'	System	30 Aug 2020 22:11:00
User entered 'None (1)'	System	30 Aug 2020 22:11:00

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:10:57', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '8d63dec7-b5f5-430e-b3f1-283dc98f9a10'	System	30 Aug 2020 22:11:00
User entered '30 Aug 2020 18:10'	System	30 Aug 2020 22:11:00

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 6'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:29', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'e597372d-2f5e-4698-9835-6ddd1a7311f4'	System	01 Sep 2020 01:07:46
User entered 'None (1)'	System	01 Sep 2020 01:07:46

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:32', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'e597372d-2f5e-4698-9835-6ddd1a7311f4'	System	01 Sep 2020 01:07:46
User entered 'No (N)'	System	01 Sep 2020 01:07:46

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:35', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'e597372d-2f5e-4698-9835-6ddd1a7311f4'	System	01 Sep 2020 01:07:46
User entered 'No (N)'	System	01 Sep 2020 01:07:46

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:40', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'e597372d-2f5e-4698-9835-6ddd1a7311f4'	System	01 Sep 2020 01:07:46
User entered 'None (1)'	System	01 Sep 2020 01:07:46

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:44', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'e597372d-2f5e-4698-9835-6ddd1a7311f4'	System	01 Sep 2020 01:07:46
User entered '31 Aug 2020 21:07'	System	01 Sep 2020 01:07:46

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 7'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:01', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '8a405efa-a400-4d6c-bf7f-8752820eba5d'	System	02 Sep 2020 01:16:27
User entered 'None (1)'	System	02 Sep 2020 01:16:27

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:00

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:06', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '8a405efa-a400-4d6c-bf7f-8752820eba5d'	System	02 Sep 2020 01:16:27
User entered 'No (N)'	System	02 Sep 2020 01:16:27

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:09', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '8a405efa-a400-4d6c-bf7f-8752820eba5d'	System	02 Sep 2020 01:16:27
User entered 'No (N)'	System	02 Sep 2020 01:16:27

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:21', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '8a405efa-a400-4d6c-bf7f-8752820eba5d'	System	02 Sep 2020 01:16:27
User entered 'None (1)'	System	02 Sep 2020 01:16:27

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:25', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '8a405efa-a400-4d6c-bf7f-8752820eba5d'	System	02 Sep 2020 01:16:27
User entered '01 Sep 2020 21:16'	System	02 Sep 2020 01:16:27

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:50', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2d7d4abb-e3f8-4ab3-92e3-f9bcedb31ced'	System	26 Aug 2020 19:51:13
User entered 'None (0)'	System	26 Aug 2020 19:51:13

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:52', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2d7d4abb-e3f8-4ab3-92e3-f9bcedb31ced'	System	26 Aug 2020 19:51:13
User entered 'None (0)'	System	26 Aug 2020 19:51:13

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:55', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2d7d4abb-e3f8-4ab3-92e3-f9bcedb31ced'	System	26 Aug 2020 19:51:13
User entered 'None (0)'	System	26 Aug 2020 19:51:13

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:50:58', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2d7d4abb-e3f8-4ab3-92e3-f9bcedb31ced' User entered 'None (0)'	System	26 Aug 2020 19:51:13
	System	26 Aug 2020 19:51:13

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:51:00', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2d7d4abb-e3f8-4ab3-92e3-f9bcedb31ced'	System	26 Aug 2020 19:51:13
User entered 'None (0)'	System	26 Aug 2020 19:51:13

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:51:03', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2d7d4abb-e3f8-4ab3-92e3-f9bcedb31ced'	System	26 Aug 2020 19:51:13
User entered 'None (0)'	System	26 Aug 2020 19:51:13

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:51:07', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2d7d4abb-e3f8-4ab3-92e3-f9bcedb31ced'	System	26 Aug 2020 19:51:13
User entered 'No (N)'	System	26 Aug 2020 19:51:13

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-26T15:51:10', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '2d7d4abb-e3f8-4ab3-92e3-f9bcedb31ced'	System	26 Aug 2020 19:51:13
User entered '26 Aug 2020 15:51'	System	26 Aug 2020 19:51:13

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 15:30'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 18:55'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 2'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:53:07', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a301d116-67bf-42c3-9198-34ad36ee98f4'	System	27 Aug 2020 20:53:51
User entered 'None (0)'	System	27 Aug 2020 20:53:51

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:53:11', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a301d116-67bf-42c3-9198-34ad36ee98f4'	System	27 Aug 2020 20:53:51
User entered 'None (0)'	System	27 Aug 2020 20:53:51

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:53:13', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a301d116-67bf-42c3-9198-34ad36ee98f4'	System	27 Aug 2020 20:53:51
User entered 'None (0)'	System	27 Aug 2020 20:53:51

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:53:16', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a301d116-67bf-42c3-9198-34ad36ee98f4'	System	27 Aug 2020 20:53:51
User entered 'None (0)'	System	27 Aug 2020 20:53:51

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:53:29', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a301d116-67bf-42c3-9198-34ad36ee98f4'	System	27 Aug 2020 20:53:51
User entered 'None (0)'	System	27 Aug 2020 20:53:51

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:53:38', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a301d116-67bf-42c3-9198-34ad36ee98f4'	System	27 Aug 2020 20:53:51
User entered 'Some interference with activity not requiring medical attention (2)'	System	27 Aug 2020 20:53:51

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:53:42', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a301d116-67bf-42c3-9198-34ad36ee98f4'	System	27 Aug 2020 20:53:51
User entered 'No (N)'	System	27 Aug 2020 20:53:51

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-27T16:53:48', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: 'a301d116-67bf-42c3-9198-34ad36ee98f4'	System	27 Aug 2020 20:53:51
User entered '27 Aug 2020 16:53'	System	27 Aug 2020 20:53:51

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 3'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T21:00:10', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '81717f82-9fb0-4068-b792-ab98271be73d'	System	29 Aug 2020 01:00:39
User entered 'None (0)'	System	29 Aug 2020 01:00:39

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T21:00:13', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '81717f82-9fb0-4068-b792-ab98271be73d'	System	29 Aug 2020 01:00:39
User entered 'None (0)'	System	29 Aug 2020 01:00:39

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T21:00:17', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '81717f82-9fb0-4068-b792-ab98271be73d'	System	29 Aug 2020 01:00:39
User entered 'None (0)'	System	29 Aug 2020 01:00:39

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T21:00:20', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '81717f82-9fb0-4068-b792-ab98271be73d'	System	29 Aug 2020 01:00:39
User entered 'None (0)'	System	29 Aug 2020 01:00:39

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T21:00:22', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '81717f82-9fb0-4068-b792-ab98271be73d'	System	29 Aug 2020 01:00:39
User entered 'None (0)'	System	29 Aug 2020 01:00:39

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T21:00:26', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '81717f82-9fb0-4068-b792-ab98271be73d'	System	29 Aug 2020 01:00:39
User entered 'None (0)'	System	29 Aug 2020 01:00:39

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T21:00:32', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '81717f82-9fb0-4068-b792-ab98271be73d'	System	29 Aug 2020 01:00:39
User entered 'No (N)'	System	29 Aug 2020 01:00:39

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-28T21:00:35', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '81717f82-9fb0-4068-b792-ab98271be73d'	System	29 Aug 2020 01:00:39
User entered '28 Aug 2020 21:00'	System	29 Aug 2020 01:00:39

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 4'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 5'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:11:02', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '310d0802-ee37-4a6e-94d0-e9ba270c2a24'	System	30 Aug 2020 22:11:36
User entered 'None (0)'	System	30 Aug 2020 22:11:36

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:11:05', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '310d0802-ee37-4a6e-94d0-e9ba270c2a24'	System	30 Aug 2020 22:11:36
User entered 'None (0)'	System	30 Aug 2020 22:11:36

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:11:08', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '310d0802-ee37-4a6e-94d0-e9ba270c2a24'	System	30 Aug 2020 22:11:36
User entered 'None (0)'	System	30 Aug 2020 22:11:36

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:11:11', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '310d0802-ee37-4a6e-94d0-e9ba270c2a24'	System	30 Aug 2020 22:11:36
User entered 'None (0)'	System	30 Aug 2020 22:11:36

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:11:15', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '310d0802-ee37-4a6e-94d0-e9ba270c2a24'	System	30 Aug 2020 22:11:36
User entered 'None (0)'	System	30 Aug 2020 22:11:36

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:11:22', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '310d0802-ee37-4a6e-94d0-e9ba270c2a24'	System	30 Aug 2020 22:11:36
User entered 'No interference with activity (1)'	System	30 Aug 2020 22:11:36

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:11:29', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '310d0802-ee37-4a6e-94d0-e9ba270c2a24'	System	30 Aug 2020 22:11:36
User entered 'No (N)'	System	30 Aug 2020 22:11:36

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-30T18:11:32', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '310d0802-ee37-4a6e-94d0-e9ba270c2a24'	System	30 Aug 2020 22:11:36
User entered '30 Aug 2020 18:11'	System	30 Aug 2020 22:11:36

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 6'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:48', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '021fe670-ef1e-4106-8bfa-f66523c71248'	System	01 Sep 2020 01:08:12
User entered 'None (0)'	System	01 Sep 2020 01:08:12

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:52', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '021fe670-ef1e-4106-8bfa-f66523c71248'	System	01 Sep 2020 01:08:12
User entered 'None (0)'	System	01 Sep 2020 01:08:12

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:54', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '021fe670-ef1e-4106-8bfa-f66523c71248'	System	01 Sep 2020 01:08:12
User entered 'None (0)'	System	01 Sep 2020 01:08:12

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:56', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '021fe670-ef1e-4106-8bfa-f66523c71248'	System	01 Sep 2020 01:08:12
User entered 'None (0)'	System	01 Sep 2020 01:08:12

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:07:58', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '021fe670-ef1e-4106-8bfa-f66523c71248'	System	01 Sep 2020 01:08:12
User entered 'None (0)'	System	01 Sep 2020 01:08:12

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:08:01', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '021fe670-ef1e-4106-8bfa-f66523c71248'	System	01 Sep 2020 01:08:12
User entered 'None (0)'	System	01 Sep 2020 01:08:12

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:08:05', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '021fe670-ef1e-4106-8bfa-f66523c71248'	System	01 Sep 2020 01:08:12
User entered 'No (N)'	System	01 Sep 2020 01:08:12

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-08-31T21:08:08', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '021fe670-ef1e-4106-8bfa-f66523c71248'	System	01 Sep 2020 01:08:12
User entered '31 Aug 2020 21:08'	System	01 Sep 2020 01:08:12

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	26 Aug 2020 19:34:02
User entered 'Day 7'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:32', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '00846e07-3bf0-4e0f-80d9-36e6b2193961'	System	02 Sep 2020 01:17:05
User entered 'None (0)'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:35', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '00846e07-3bf0-4e0f-80d9-36e6b2193961'	System	02 Sep 2020 01:17:05
User entered 'None (0)'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:39', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '00846e07-3bf0-4e0f-80d9-36e6b2193961'	System	02 Sep 2020 01:17:05
User entered 'None (0)'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:41', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '00846e07-3bf0-4e0f-80d9-36e6b2193961'	System	02 Sep 2020 01:17:05
User entered 'None (0)'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:45', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '00846e07-3bf0-4e0f-80d9-36e6b2193961'	System	02 Sep 2020 01:17:05
User entered 'None (0)'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:53', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '00846e07-3bf0-4e0f-80d9-36e6b2193961'	System	02 Sep 2020 01:17:05
User entered 'No interference with activity (1)'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:16:58', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '00846e07-3bf0-4e0f-80d9-36e6b2193961'	System	02 Sep 2020 01:17:05
User entered 'No (N)'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-01T21:17:02', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '00846e07-3bf0-4e0f-80d9-36e6b2193961'	System	02 Sep 2020 01:17:05
User entered '01 Sep 2020 21:17'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 19:34:02

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 01:17:05
User entered 'Day 8'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:00

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-03T11:01:01', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '51f8a673-d435-4ac7-82ab-ec8f90e37704'	System	03 Sep 2020 15:01:08
User entered 'No interference with activity (1)'	System	03 Sep 2020 15:01:08

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-03T11:01:05', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '51f8a673-d435-4ac7-82ab-ec8f90e37704'	System	03 Sep 2020 15:01:08
User entered '03 Sep 2020 11:01'	System	03 Sep 2020 15:01:08

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 01:17:05
User entered 'Day 9'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(9)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:01:08
User entered 'Day 10'	System	03 Sep 2020 15:01:08

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:01:08

US3412328

Folder: Diary Dose 1 (1)

Form: Chills_Day(10)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:01:08

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 01:17:05
User entered 'Day 8'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:00

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 (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-03T11:01:12', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '5e16b49e-b770-4688-8840-3c8c90127b04'	System	03 Sep 2020 15:01:16
User entered 'No (N)'	System	03 Sep 2020 15:01:16

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3AB88A90-FC84-420E-A0B6-74633AFE7527)', Time: '2020-09-03T11:01:15', User OID: 'PatientReportedOutcome (US3412328)', ODM File OID: '5e16b49e-b770-4688-8840-3c8c90127b04'	System	03 Sep 2020 15:01:16
User entered '03 Sep 2020 11:01'	System	03 Sep 2020 15:01:16

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 01:17:05
User entered 'Day 9'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 01:17:05

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 15:01:08
User entered 'Day 10'	System	03 Sep 2020 15:01:08

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 15:01:08

US3412328

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 15:01:08

US3412328

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Was Contact Attempted?](#)

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

US3412328

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

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

US3412328

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Sep 2020 17:16:57

US3412328

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Comments](#)

If Contact Not Made, please provide Comments

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

US3412328

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 17:17:04

US3412328

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 17:17:04

US3412328

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	09 Sep 2020 18:03:34

US3412328

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Mason Urban (b) (4) (b) (4)	09 Sep 2020 18:03:34

US3412328

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	09 Sep 2020 18:03:34

US3412328

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	09 Sep 2020 18:03:34

US3412328

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	09 Sep 2020 18:03:41

US3412328

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 18:03:41

US3412328

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	16 Sep 2020 17:47:12

US3412328

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	Mason Urban (b) (4) (b) (4)	16 Sep 2020 17:47:12

US3412328

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	16 Sep 2020 17:47:12

US3412328

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	16 Sep 2020 17:47:12

US3412328

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	16 Sep 2020 17:47:17

US3412328

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 17:47:17

US3412328

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	15 Oct 2020 15:30:20
Query 'Why does this say No? Visit was performed, subject was just not dosed? Please consider changing to Yes' answered with 'UPDATED' (Site from CRA).	Mylene Asmar-Rios (b) (4)	13 Oct 2020 21:09:58
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	13 Oct 2020 21:09:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	13 Oct 2020 21:09:09
User opened query 'Why does this say No? Visit was performed, subject was just not dosed? Please consider changing to Yes' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 13:38:32
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:27:02

US3412328

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 19:08:13
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'per epip this was noted and subject was allowed to continue in the study' (Site from System).	Steven Anderson (b) (4)	15 Oct 2020 15:33:15
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	15 Oct 2020 15:30:20
User entered '06 Oct 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Oct 2020 15:30:20
User entered empty.	Jacob sekinger (b) (4)	28 Sep 2020 18:27:02

US3412328

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	13 Oct 2020 21:09:45
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	13 Oct 2020 21:09:45
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	13 Oct 2020 21:09:09
User entered empty.	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:27:02

US3412328

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	28 Sep 2020 18:27:02

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '15:35'	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '06 Oct 2020 15:35'	System	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

Pulse (xxx)

Audit	User	Time (GMT)
User entered '68'	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '16'	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '94'	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '68'	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 18:38:01
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:38:01
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:37:46
User entered empty.	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:38:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Oct 2020 18:38:01
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:37:46
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:38:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Oct 2020 18:38:01
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:37:46
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:38:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Oct 2020 18:38:01
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:37:46
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:38:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Oct 2020 18:38:01
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:37:46
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:38:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Oct 2020 18:38:01
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:37:46
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:38:01
Query 'Data is required. Please provide.' answered by System data change (Site from System).		08 Oct 2020 18:38:01
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Oct 2020 18:37:46
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:37:46
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:37:46

US3412328

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Oct 2020 18:38:16
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	Steven Anderson (b) (4)	08 Oct 2020 18:38:16
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
Query 'Please complete Dosing Discontinuation CRF in End of Study Folder' answered with 'NOTE ON VISIT 2 DATED 06-OCT-2020 NOTE THAT PATIENT WILL NOT BE RECEIVING POST INJECTION ARM HOWER WNL' (Site from CRA).	Melissa Fuson (b) (4)	05 Nov 2020 15:36:52
User opened query 'Please complete Dosing Discontinuation CRF in End of Study Folder' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 01:10:21
User closed query 'Please complete dosing discontinuation page in End of Study Folder' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 01:10:21
Query 'Please complete dosing discontinuation page in End of Study Folder' answered with 'PROTOCOL DEVIATIONS / EXVEPTIONS / VIOLATIONS PAGE WAS FILLED OUT.' (Site from CRA).	Melissa Fuson (b) (4)	26 Oct 2020 15:44:59
User opened query 'Please complete dosing discontinuation page in End of Study Folder' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 13:37:36
User entered 'No (N)'	Steven Anderson (b) (4)	08 Oct 2020 18:38:23

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

[If No, reason not given](#)

Audit	User	Time (GMT)
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		08 Oct 2020 18:39:21
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 18:39:21
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	08 Oct 2020 18:38:23
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:38:23

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User		Time (GMT)
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	(b) (4)	08 Oct 2020 18:39:21
User entered 'patients decision to not dose due to side effects from first dose' reason for change: Data Entry Error	Steven Anderson (b) (4)	(b) (4)	08 Oct 2020 18:39:01
User entered empty.	Steven Anderson (b) (4)	(b) (4)	08 Oct 2020 18:38:23

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:38:23

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:38:23
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:38:23
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:38:23

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:38:23
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:38:23

US3412328

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:38:23

US3412328

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Oct 2020 18:39:43
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '06 Oct 2020'	Steven Anderson (b) (4)	08 Oct 2020 18:39:43
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '16:00'	Steven Anderson (b) (4)	08 Oct 2020 18:39:43
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '06 Oct 2020 16:00'	System	08 Oct 2020 18:39:43

US3412328

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:00

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 14:20:23
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		19 Oct 2020 14:20:23
User entered '06 Oct 2020' reason for change: Data Entry Error	Jacob sekinger (b) (4)	19 Oct 2020 14:20:23
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	15 Oct 2020 15:30:20
User entered '08 Oct 2020'	Steven Anderson (b) (4)	08 Oct 2020 18:40:04

US3412328

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	08 Oct 2020 18:40:04

US3412328

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Oct 2020 18:40:04
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '16:15'	Steven Anderson (b) (4)	08 Oct 2020 18:40:04
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '06 Oct 2020 16:15'	System	19 Oct 2020 14:20:23
User entered '08 Oct 2020 16:15'	System	08 Oct 2020 18:40:04

US3412328

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	08 Oct 2020 18:40:04

US3412328

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Steven Anderson (b) (4)	08 Oct 2020 18:40:04
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4)	08 Oct 2020 18:40:04
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	08 Oct 2020 18:40:04

US3412328

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Oct 2020 18:40:10
	(b) (4)	

US3412328

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 18:40:10

US3412328

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Oct 2020 16:24:02

US3412328

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Mason Urban (b) (4) (b) (4)	13 Oct 2020 16:24:02

US3412328

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	13 Oct 2020 16:24:02

US3412328

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	13 Oct 2020 16:24:02

US3412328

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	13 Oct 2020 16:24:07

US3412328

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 16:24:07

US3412328

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	20 Oct 2020 15:05:13

US3412328

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Mason Urban (b) (4) (b) (4)	20 Oct 2020 15:05:13

US3412328

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	20 Oct 2020 15:05:13

US3412328

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	20 Oct 2020 15:05:13

US3412328

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	20 Oct 2020 15:05:17

US3412328

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 15:05:17

US3412328

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	27 Oct 2020 15:26:12

US3412328

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Mason Urban (b) (4) (b) (4)	27 Oct 2020 15:26:12

US3412328

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	27 Oct 2020 15:26:12

US3412328

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Mason Urban (b) (4) (b) (4)	27 Oct 2020 15:26:12

US3412328

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	27 Oct 2020 15:26:56

US3412328

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 15:26:56

US3412328

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:02

US3412328

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '3 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:02

US3412328

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:02

US3412328

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	03 Nov 2020 15:42:02

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 15:42:36

US3412328

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:47

US3412328

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:42:47

US3412328

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:43:06

US3412328

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '3 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:43:06

US3412328

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '09:07'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:43:06

US3412328

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '3 Nov 2020 09:07'	System	03 Nov 2020 15:43:06

US3412328

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:43:14

US3412328

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 15:43:14

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:21:22

US3412328

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:21:22
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:21:22

US3412328

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:00

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	28 Sep 2020 18:35:07
User entered 'No (N)'	Jacob sekinger (b) (4)	03 Sep 2020 20:54:05

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 04:15:57
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 16:36:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	29 Oct 2020 16:36:35
Data point term sent to Coder	System	26 Oct 2020 15:54:09
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'CHEST PAIN (ETIOLOGY - UNDETERMINED)' (Site from DM).	Melissa Fuson (b) (4)	26 Oct 2020 15:53:39
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' (Site from System).	System	26 Oct 2020 15:53:35
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' answered with 'CHEST PAIN (ETIOLOGY - UNDETERMINED)' (Site from System).	Melissa Fuson (b) (4)	26 Oct 2020 15:53:35
Coding entries removed.	Melissa Fuson (b) (4)	26 Oct 2020 15:53:15

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'CHEST PAIN (ETIOLOGY - UNDETERMINED)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 15:53:15
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' (Site from System).	Coder Import (b) (4)	25 Oct 2020 16:45:29
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 00:03:48
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:39:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 18:39:42
Data point term sent to Coder	System	28 Sep 2020 18:38:47
User entered 'chest pain'	Jacob sekinger (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'per source, start date is 05 Sep 2020? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 01:07:46
Query 'per source, start date is 05 Sep 2020? Please confirm and update accordingly' answered with 'This is the correct start date and us been updted in EDC' (Site from CRA).	Steven Anderson (b) (4)	24 Nov 2020 16:50:14
User entered '05 Sep 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 16:49:29
User opened query 'per source, start date is 05 Sep 2020? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:47:43
User entered '17 Sep 2020'	Jacob sekinger (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 18:49:49
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Oct 2020 18:50:03
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	08 Oct 2020 18:50:03
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Oct 2020 18:49:49
User entered '01 Oct 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 18:49:49
User entered empty.	Jacob sekinger (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:48:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 16:51:54
Query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' answered with 'this is correct reason as to why the subject withdrew IP' (Site from DM).	Steven Anderson (b) (4)	24 Nov 2020 16:51:11
User opened query 'Per CDM: there are more than 1 record with action of IP Withdrawn. Please review and reconcile as the main reason (only 1 record) for IP Withdrawn should be recorded.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 22:45:45
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 11:19:32
User closed query 'Per CDM re-query: Please complete the Dosing discontinuation eCRF under End of Study folder, as the action taken with Investigational Product = Investigational Product Withdrawn. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:45:40
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'SUBJECT HAD CHEST PAIN BETWEEN VISIT 1 AND VISIT 2. SUBJECT WAS MEDICALLY CLEARED AND FELT FINE DURING VISIT 2, BUT DECIDED THAT THEY WILL NOT GET THE SECOND DOSAGE. SUBJECT WILL CONTINUE STUDY' (Site from System).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 21:02:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	05 Nov 2020 15:53:53
Query 'Per CDM re-query: Please complete the Dosing discontinuation eCRF under End of Study folder, as the action taken with Investigational Product = Investigational Product Withdrawn. Please update accordingly else clarify. ' answered with 'END OF STUDY FOLDER DOSING DISCONTINUATION HAS BEEN UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 15:48:38
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation record that match this information. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:45:57
User opened query 'Per CDM re-query: Please complete the Dosing discontinuation eCRF under End of Study folder, as the action taken with Investigational Product = Investigational Product Withdrawn. Please update accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:45:52
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation record that match this information. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'SHOULD NOT HAVE BEEN CON MED IT SHOULD HAVE BEEN CON PROCEDURE - UPDATED' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 13:41:07
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. However, there is no corresponding Dosing Discontinuation record that match this information. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:24:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Oct 2020 18:44:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Oct 2020 18:44:04
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 18:44:04
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 18:38:25
User entered empty.	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[None](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 00:16:44
	(b) (4)	
User entered '0'	Jacob sekinger (b) (4)	28 Sep 2020 18:38:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 00:16:44
User entered '1' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 15:49:41
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 04:21:46
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'SHOULD HAVE BEEN CONMITANT PROCEDURE NOT CON MEDICATION - UPDATED TO REFLECT' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	29 Oct 2020 13:41:45
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Oct 2020 13:39:43
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Oct 2020 15:29:17
User entered '1'	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Thank you for updating to other action taken=Con Medication. However there is no corresponding medication recorded in CM form. Please review and add the Con Med else please review if action taken can be updated to 'none'. Please update as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:19:39
Query 'Per CDM re-query: Thank you for updating to other action taken=Con Medication. However there is no corresponding medication recorded in CM form. Please review and add the Con Med else please review if action taken can be updated to 'none'. Please update as appropriate else clarify. ' answered with 'sorry for the confusion there is no corresponding medication. subject did not take anything of AE' (Site from DM).	Steven Anderson (b) (4)	11 Nov 2020 00:16:40
User closed query 'Per CDM: Other Action Taken = Concomitant Procedure, however there is no Concomitant Procedure recorded. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:51:35
User opened query 'Per CDM re-query: Thank you for updating to other action taken=Con Medication. However there is no corresponding medication recorded in CM form. Please review and add the Con Med else please review if action taken can be updated to 'none'. Please update as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 06:51:33
Query 'Per CDM: Other Action Taken = Concomitant Procedure, however there is no Concomitant Procedure recorded. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'OTHER ACTION HAS BEEN UPDTED TO CON-MED' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 15:49:56
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 15:49:41
User opened query 'Per CDM: Other Action Taken = Concomitant Procedure, however there is no Concomitant Procedure recorded. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 04:22:56

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Oct 2020 13:39:43
User entered '0'	(b) (4) Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 18:50:03
User entered 'Unknown (UNKNOWN)'	Jacob sekinger (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 18:38:25

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:55
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:13
User entered 'USA-US061-2020-mRNA-1273-P301000010'	System	12 Nov 2020 01:48:06
User entered 'New'	(b) (4), (b) (6)	12 Nov 2020 01:48:06

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:56
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:35:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:35:47
Data point term sent to Coder	System	11 Nov 2020 00:21:49
User entered 'Atypical chest pain'	Steven Anderson (b) (4) (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:58
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:04:00
User entered 'No (N)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:07:11
User entered 'No (N)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Steven Anderson (b) (4) (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:07:12
User entered empty.	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:07:14
User entered 'No (N)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:07:20
User entered '18 Sep 2020'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:07:22
User entered empty.	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:07:24
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:07:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:07:00
User entered '0'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:07:02
User entered '0'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:57
User entered '1'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:55
User entered '17 Sep 2020'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39
	(b) (4)	

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:51
User entered '18 Sep 2020'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39
	(b) (4)	

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:49
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	11 Nov 2020 00:21:54
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		11 Nov 2020 00:21:54
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 00:21:54
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4)	
	System	11 Nov 2020 00:21:39
User entered 'Unknown (UNK)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39
	(b) (4)	

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:46
User entered '0'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:44
User entered '0'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:38
User entered '0'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:36
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:34
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	24 Nov 2020 20:30:37
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		11 Nov 2020 00:22:12
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	11 Nov 2020 00:22:12
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	11 Nov 2020 00:21:39
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[None](#)

Audit	User	Time (GMT)
User entered '1'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39
	(b) (4)	

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Steven Anderson (b) (4) (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:14
User entered empty.	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:06:12
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please provide results from echocardiogram if available.' answered with 'this is not available due to site being unable to obtain medical records per the narrative. ' (Site from Safety).	Steven Anderson (b) (4)	24 Nov 2020 16:54:09
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:34:59
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.' canceled (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:34:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please provide results from echocardiogram if available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:34:40
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:34:30
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)	20 Nov 2020 21:34:21

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Due to chest pressure subject was advised to go to ER for evaluation. per er doctor subject was admitted overnight for observation. Subject's testing has all been negative for any cardiac issues. Subject has no other complaints, no fever, no shortness of breath, subject had an echocardiogram before discharge. Site attempted to obtain medical records. However, subject refused release of any medical records from her stay. Site was only able to confirm SAE diagnosis due to ER doctor confirming subject was admitted to the hospital overnight for observation. Subject has since resolved all issues and site is unable to do any further follow up without medical records.'	Steven Anderson (b) (4)	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 00:21:39

US3412328

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:00

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 00:21:39

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:00

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:36:32

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:05:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:05:22
Data point term sent to Coder	System	03 Nov 2020 15:34:06
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:33:26
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:33:26
User entered 'FLONASE, OTC (FLUTICASONE)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:33:26
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:39:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:39:43
Data point term sent to Coder	System	17 Sep 2020 17:38:54
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' canceled (Site from System).	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:38:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:37:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 17:37:35
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	04 Sep 2020 11:52:31
Data point term sent to Coder	System	03 Sep 2020 20:38:39
User entered 'Flonase, OTC'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'ALLERGIC RHINITIS - SEASONAL'	Melissa Fuson (b) (4)	03 Nov 2020 15:33:26
reason for change: Data Entry Error	(b) (4)	
User entered 'allergic rhinitis'	Jacob sekinger (b) (4)	03 Sep 2020 20:37:57
	(b) (4)	

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'puff (PUFF)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 20:37:57

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS AND ESTROGENS IN COMBINATION, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:22:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:22:56
Data point term sent to Coder	System	03 Sep 2020 20:39:47
User entered 'norethindrone acetat-ethinyl'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Indication](#)

Audit	User	Time (GMT)
User entered '.osteopenia'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.5/2.5).' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 07:34:32
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.5/2.5).' answered with 'the combination has been added' (Site from DM).	Steven Anderson (b) (4)	08 Oct 2020 18:51:33
User entered '0.5/2.5' reason for change: Data Entry Error	(b) (4)	08 Oct 2020 18:51:18
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.5/2.5).' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 04:09:59
User entered '0.5'	Jacob sekinger (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 03:55:04
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'the dosing unit has been updated to the appropriate one' (Site from DM).	Steven Anderson (b) (4)	08 Oct 2020 18:51:50
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	08 Oct 2020 18:51:18
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 04:10:07
User entered 'mg (mg)'	Jacob sekinger (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'mcg' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 18:51:18
User entered empty.	Jacob sekinger (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un May 2020'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 20:39:28

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 02:54:04
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 02:54:04
Data point term sent to Coder	System	22 Oct 2020 16:12:13
User closed query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	System	22 Oct 2020 16:11:41
Query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' answered with 'VIEW AND UPDATED FROM SOURCE - 1G OF TOPICAL CREAM TAKEN' (Site from System).	Melissa Fuson (b) (4) (b) (4)	22 Oct 2020 16:11:41
Data point term sent to Coder	System	22 Oct 2020 16:11:12
Data point term sent to Coder	System	22 Oct 2020 16:10:07
User entered 'CREAM FOR PAIN - BACLOFEN, DICLOFENAC, GABAPENTIN, LIDOCAINE -' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Oct 2020 16:09:43
Data point term sent to Coder	System	22 Oct 2020 16:09:02
User entered 'BACLOFEN, DICLOFENAC, GABAPENTIN, LIDOCAINE - CREAM FOR PAIN' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Oct 2020 16:08:38
User opened query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	Coder Import (b) (4) (b) (4)	07 Sep 2020 12:29:40
Data point term sent to Coder	System	03 Sep 2020 20:40:51
User entered 'compound cream for pain'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'pain for foot'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: As per CCGs, please provide dose in numerical values for this field otherwise enter 'UNK' if the dose is unknown.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:44:12
Query 'Per CDM: As per CCGs, please provide dose in numerical values for this field otherwise enter 'UNK' if the dose is unknown.' answered with 'TOPICAL CREAM' (Site from DM).	Melissa Fuson (b) (4)	22 Oct 2020 16:10:49
User entered '1' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 16:10:22
User opened query 'Per CDM: As per CCGs, please provide dose in numerical values for this field otherwise enter 'UNK' if the dose is unknown.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:11:20
User entered 'topical'	Jacob sekinger (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'TOPICAL CREAM - 1G' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Oct 2020 16:09:43
User entered 'topical cream'	Jacob sekinger (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:44:23
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'VIEWED SOURCE AND TOPICAL IS HOW THEY HAVE ADMINISTERED' (Site from DM).	Melissa Fuson (b) (4)	22 Oct 2020 16:13:53
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 16:11:10
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 04:10:36
User entered 'Transdermal (TRANSDERMAL)'	Jacob sekinger (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:40:34

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name (e.g BENZOYL PEROXIDE 2.5%) as there are multiple strengths available for this medication. Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:19:02
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name (e.g BENZOYL PEROXIDE 2.5%) as there are multiple strengths available for this medication. Review and amend as appropriate.' answered with 'UNKNOWN - SOURCE ONLY HAS 1 PUMP' (Site from DM).	Melissa Fuson (b) (4)	03 Nov 2020 15:37:54
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name (e.g BENZOYL PEROXIDE 2.5%) as there are multiple strengths available for this medication. Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:36:00
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: PEROXIDES, PRODUCT: BENZOYL PEROXIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Oct 2020 00:02:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Oct 2020 00:02:46
Data point term sent to Coder	System	08 Oct 2020 19:01:18
Coding entries removed.	Steven Anderson (b) (4)	08 Oct 2020 19:00:55
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTI-ACNE PREPARATIONS, ATC: ANTI-ACNE PREPARATIONS FOR TOPICAL USE, ATC: PEROXIDES, PRODUCT: BENZOYL PEROXIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Sep 2020 06:15:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Sep 2020 06:15:35
Data point term sent to Coder	System	03 Sep 2020 20:41:54
User entered 'benzoyl peroxide'	Jacob sekinger (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	03 Nov 2020 15:38:51
User entered 'No (N)'	Jacob sekinger (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:17:57
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'CHANGED PROPHYLAXIS TO YES. AS PER SOURCE THIS IS BEING USED FOR GENERAL SKIN CARE HEALTH' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 15:39:20
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:43:09
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:42:59
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:39:09
User closed query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:02:24
Query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'this is updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Oct 2020 19:01:04

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'General Skin Care' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 19:00:55
User opened query 'Per DM CLR: Please note there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 04:10:49
User entered 'acne'	Jacob sekinger (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'pump'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Route of administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:02:31
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4)	08 Oct 2020 19:01:19
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Oct 2020 19:00:55
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 04:10:56
User entered 'Transdermal (TRANSDERMAL)'	Jacob sekinger (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 20:41:52

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 20:44:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 20:44:47
Data point term sent to Coder	System	03 Sep 2020 20:43:11
User entered 'calcium'	Jacob sekinger (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1200'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 20:42:48

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 20:45:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Sep 2020 20:45:52
Data point term sent to Coder	System	03 Sep 2020 20:44:13
User entered 'vitamin D'	Jacob sekinger (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'general health'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 11:19:12
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UNKNOWN PER SOURCE ONLY HAS 1 TABLET' (Site from DM).	Melissa Fuson (b) (4)	03 Nov 2020 15:37:01
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:48:15
User entered '1'	Jacob sekinger (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'tablet (TABLET)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Sep 2020 20:43:33

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 14:43:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 14:43:20
Data point term sent to Coder	System	03 Nov 2020 14:41:54
User entered 'pepcid'	Jacob sekinger (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'GERD'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

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

Audit	User	Time (GMT)
User entered '29 Oct 2020'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Nov 2020 14:41:23

US3412328

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:23:00

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	03 Sep 2020 20:54:18

US3412328

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:23:00

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 15:53:53

US3412328

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:23:00

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Query 'Please consider updating to other since subject was medically cleared for 2nd dose but declined' answered with 'Subject decided to withdraw study IP. therefor other will be listed' (Site from CRA).	Steven Anderson (b) (4)	24 Nov 2020 20:31:04
User entered 'Other (OTHER)' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 20:30:37
User opened query 'Please consider updating to other since subject was medically cleared for 2nd dose but declined' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 15:04:59
User entered 'SAE (specify) (SAE)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Nov 2020 00:22:12
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 15:53:53

US3412328

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:23:00

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:49:24
Query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' answered with 'Subject decided to withdraw study IP. therefor other will be listed' (Site from DM).	Steven Anderson (b) (4)	24 Nov 2020 20:31:05
User opened query 'Per CDM: please record SAE record number (i.e. SAE #1, etc.) instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:07:19
User entered 'Subject had chest pain between visit 1 and visit 2. Subject was medically cleared of symptoms by visit 2, but has decided that they did not want the second dosage. Subject will continue in study.'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 15:53:53

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'USA-US061-2020-MRNA-1273-P301000010'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'Yes (Y)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'No (N)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'No (N)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'Yes (Y)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'No (N)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'No (N)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'No (N)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'Gregory'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'Gottschlich'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered '4260 Glendale Milford Road'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'Cincinnati'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered '45242'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
User entered 'US'	System	12 Nov 2020 01:48:37

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 01:48:37

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'USA-US061-2020-MRNA-1273-P301000010'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'Yes (Y)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'No (N)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'No (N)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'Yes (Y)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'No (N)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'No (N)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'No (N)'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'Gregory'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'Gottschlich'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered '4260 Glendale Milford Road'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered 'Cincinnati'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 01:48:31
User entered '45242'	System	12 Nov 2020 01:48:06

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
User entered 'US'	System	12 Nov 2020 01:48:37

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:00

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 01:48:37

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:00

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:08:14
User entered '12/Nov/2020 01:48'	System	12 Nov 2020 01:48:37

US3412328

Folder: SAE USA-US061-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:00

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)	25 Nov 2020 01:08:14
User entered '1'	(b) (4), (b) (6)	12 Nov 2020 01:48:37