

US3012118 (Prod: Benchmark Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:43:00

All time stamps listed in this document are displayed in GMT

US3012118

Form: Participant Creation

Generated On: 26 Nov 2020 08:43:00

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

Date of Birth (MMM yyyy)	(b) (6) 1993
Age	27
Age Units	YEARS
Age (Derived)	27
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

Date of Informed Consent (<i>dd MMM yyyy</i>)	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:43:00

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

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:43:00

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

Condition	ALLERGIC TO SULFA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

Condition	ANEMIA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

Condition	HERPES SIMPLEX II
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

Condition	MILD DEPRESSION
Start date (dd MMM yyyy)	UN OCT 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 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 08:43:00

Condition	MILD ANXIETY
Start date (dd MMM yyyy)	UN OCT 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

Condition	BIPOLAR DISORDER TYPE 2
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

Condition	ALCOHOL ADDICTION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:58 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 13:58
Height (<i>xxx.x</i>)	65.0 in
Weight (<i>xxx.x</i>)	151.6 lb
BMI (<i>xxx.x</i>)	25.28031 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 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 08:43:00

Date of assessment (*dd MMM yyyy*) 12 AUG 2020

Is the participant of childbearing potential? Yes ☒ No ☐

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	12 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

Occupational Risk

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

Specify

Location and Living Circumstances Risk (check all that apply)

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:00

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 103303

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 08:43:00

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 08:43:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	13:58 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 13:58
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 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 08:43:00

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 AUG 2020
Time of assessment (00:00-23:59)	16:20 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 16:20
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

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: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (*dd MMM yyyy*) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	12 AUG 2020
What was the treatment time? (00:00-23:59)	15:49 (24 HR)
Treatment Date and Time (derived)	12 AUG 2020 15:49
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	12 AUG 2020
Collection time (<i>00:00-23:59</i>)	14:03 (24 HR)
Collection date and time (derived)	12 AUG 2020 14:03

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:00

Collection date (<i>dd MMM yyyy</i>)			12 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	15:05	12 AUG 2020 15:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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 08:43:00

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 12 AUG 2020 16:21

PC Open Date & Time 12 AUG 2020 16:09

PC Close Date & Time 12 AUG 2020 18:39

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

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 98.3 °F

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

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

PC Time Stamp	12 AUG 2020 19:40
PC Open Date & Time	12 AUG 2020 19:34
PC Close Date & Time	13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:00

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

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 18:52

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:00

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 12:02

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:00

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

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

15 AUG 2020 21:16

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:00

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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 23:25

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:00

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 21:51

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:00

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 17:15

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 16:21

PC Open Date & Time

12 AUG 2020 16:09

PC Close Date & Time

12 AUG 2020 18:39

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 19:38

PC Open Date & Time

12 AUG 2020 19:34

PC Close Date & Time

13 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:00

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

13 AUG 2020 19:00

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:00

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

14 AUG 2020 12:02

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:00

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 ☒

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

15 AUG 2020 21:16

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:00

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

16 AUG 2020 23:26

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:00

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

17 AUG 2020 21:53

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:00

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

18 AUG 2020 17:16

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 16:22
PC Open Date & Time	12 AUG 2020 16:09
PC Close Date & Time	12 AUG 2020 18:39

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 19:39
PC Open Date & Time	12 AUG 2020 19:34
PC Close Date & Time	13 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

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 ☒

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 19:00
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

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 ☒

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 12:03
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

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 ☒

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:33
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

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 ☒

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 23:26
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

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 ☒

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:53
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

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 ☒

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 17:16
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 19 AUG 2020 23:52

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 19 AUG 2020 23:53

PC Open Date & Time 19 AUG 2020 12:00

PC Close Date & Time 20 AUG 2020 11:59

US3012118

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	19 AUG 2020 23:53
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3012118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

Was Contact Attempted?

Yes ☒

No ☐

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

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012118

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

Was Contact Attempted?

Yes ☒

No ☐

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

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012118

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

Was Contact Attempted?

Yes ☒

No ☐

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

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

PT DID NOT RESPOND OR CALL
BACK

If Contact Not Made, please provide Comments

US3012118

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 SEP 2020
Time of assessment (00:00-23:59)	12:57 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 12:57
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
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 <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3012118

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3012118

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	09 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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?

US3012118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	09 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:37 (24 HR)
Collection date and time (derived)	09 SEP 2020 13:37

US3012118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:00

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:27	09 SEP 2020 13:27
Nasopharyngeal Swab 2	No		

US3012118

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

Was Contact Attempted?

Yes ☒

No ☐

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

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012118

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012118

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

Was Contact Attempted?

Yes ☒

No ☐

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

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012118

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:00 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 09:00
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012118

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

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.

US3012118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	7 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:10 (24 HR)
Collection date and time (derived)	7 OCT 2020 09:10

US3012118

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

DAY 64

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

12 OCT 2020 12:34:47

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 00:01:22

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

DAY 78

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 12:15:28

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

DAY 92

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 18:39:29

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

DAY 99

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 13:20:57

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2020 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2020 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
---	--

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	24 DEC 2021 00:01
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Patient Cloud Close Date & Time	28 DEC 2021 23:59
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US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
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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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
---	--

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 ☐

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
---	--

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

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 <input type="checkbox"/>
---	--

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

US3012118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

Was Contact Attempted?

Yes ☒

No ☐

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

04 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3012118

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3012118

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3012118

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 08:43:00

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3012118

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:43:00

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

AEID	
Adverse event	INTERMITTENT HEADACHES
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	316 of 1433

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

AEID	
Adverse event	MUSCLE ACHES ALL OVER BODY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	19 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	
318 of 1433	

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

AEID	
Adverse event	SYNCOPE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	9 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	9 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	320 of 1433

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:43:00

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

Yes ☒

No ☐

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

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

Name of Medication	LAMOTRIGINE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	BIPOLAR DISORDER
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

Name of Medication	TRAZADONE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	BIPOLAR DISORDER
Dose per administration	50
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

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

US3012118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:43:00

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3012118

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:00

Date of dosing discontinuation (dd MMM yyyy)

17 AUG 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 _____

US3012118

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:43:00

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 ☐

Audit

US3012118 (Prod: Benchmark Research)

US3012118

Form: Participant Creation

Generated On: 26 Nov 2020 08:43:00

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3012118'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 18:54:34

US3012118

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:22

US3012118

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 18:54:35

US3012118

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:22

US3012118

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	12 Aug 2020 20:42:22

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered (b) (6) 1993'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 18:54:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Age](#)

Audit	User	Time (GMT)
User entered '27'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '27'	System	12 Aug 2020 20:42:47

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[White](#)

Audit	User	Time (GMT)
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:00

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:36

US3012118

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:47

US3012118

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	12 Aug 2020 20:42:47

US3012118

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '2020'	System	12 Aug 2020 20:42:47

US3012118

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:47

US3012118

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:47

US3012118

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:47

US3012118

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:47

US3012118

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:47

US3012118

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 18:54:35

US3012118

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:00

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Aug 2020 20:42:50

US3012118

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:42:50

US3012118

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:43:00

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:21:28

US3012118

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:23:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:23:17
Data point term sent to Coder	System	13 Aug 2020 01:22:49
User entered 'allergic to sulfa'	Tambra Dora (b) (4)	13 Aug 2020 01:22:42
	(b) (4)	

US3012118

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:22:42

US3012118

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:22:42

US3012118

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:22:42

US3012118

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:22:42

US3012118

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:22:42

US3012118

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	13 Aug 2020 01:22:42

US3012118

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '2018'	System	13 Aug 2020 01:22:42

US3012118

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 01:22:42

US3012118

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 01:22:42

US3012118

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:25:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 01:25:19
Data point term sent to Coder	System	13 Aug 2020 01:23:49
User entered 'anemia'	Tambra Dora (b) (4)	13 Aug 2020 01:23:29
	(b) (4)	

US3012118

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:23:29

US3012118

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:23:29

US3012118

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:23:29

US3012118

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:23:29

US3012118

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:23:29

US3012118

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	13 Aug 2020 01:23:29

US3012118

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '2018'	System	13 Aug 2020 01:23:29

US3012118

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	13 Aug 2020 01:23:29

US3012118

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '2018'	System	13 Aug 2020 01:23:29

US3012118

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type II - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:23:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:23:19
Data point term sent to Coder	System	13 Aug 2020 01:24:50
User entered 'herpes simplex II'	Tambra Dora (b) (4)	13 Aug 2020 01:24:11
	(b) (4)	

US3012118

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:24:11

US3012118

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:24:11

US3012118

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:24:11

US3012118

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:24:11

US3012118

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:24:11

US3012118

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	13 Aug 2020 01:24:11

US3012118

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '2017'	System	13 Aug 2020 01:24:11

US3012118

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 01:24:11

US3012118

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 01:24:11

US3012118

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:49:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:49:08
Data point term sent to Coder	System	13 Aug 2020 21:48:02
User entered 'Mild Depression'	Katherine Davis (b) (4)	13 Aug 2020 21:47:51
	(b) (4)	

US3012118

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'un Oct 2015'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:47:51

US3012118

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:47:51

US3012118

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:47:51

US3012118

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:47:51

US3012118

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:47:51

US3012118

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Oct 2015'	System	13 Aug 2020 21:47:51

US3012118

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '2015'	System	13 Aug 2020 21:47:51

US3012118

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:47:51

US3012118

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:47:51

US3012118

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:50:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:50:18
Data point term sent to Coder	System	13 Aug 2020 21:49:03
User entered 'mild anxiety'	Katherine Davis (b) (4)	13 Aug 2020 21:48:22
	(b) (4)	

US3012118

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'un Oct 2015'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:48:22

US3012118

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:48:22

US3012118

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:48:22

US3012118

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:48:22

US3012118

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:48:22

US3012118

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Oct 2015'	System	13 Aug 2020 21:48:22

US3012118

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '2015'	System	13 Aug 2020 21:48:22

US3012118

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:48:22

US3012118

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:48:22

US3012118

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 07:47:27
Query 'Per DM CLR: Please note that there is no Con Jennifer Leyva Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' answered with 'Per subject, is treated with therapy and not meds' (Site from DM).	(b) (4)	28 Sep 2020 23:09:27
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation. ' (Site from DM).	(b) (4), (b) (6)	26 Aug 2020 09:06:51
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar II disorder, LLT: Bipolar II disorder - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 23:24:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Aug 2020 23:24:10
Data point term sent to Coder	System	13 Aug 2020 21:49:05
User entered 'Bipolar disorder Type 2'	Katherine Davis (b) (4)	13 Aug 2020 21:49:01

US3012118

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Condition start date = UN UNK 2020. Per CCGs page 22 only conditions that started before the Informed Consent was signed are to be reported on the MH eCRF. Please review and confirm the start date is prior to the Informed consent date, else update as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:43:53
Query 'Per CDM: Condition start date = UN UNK 2020. Per CCGs page 22 only conditions that started before the Informed Consent was signed are to be reported on the MH eCRF. Please review and confirm the start date is prior to the Informed consent date, else update as per CCGs. ' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4)	27 Oct 2020 15:22:13
User entered 'UN Jan 2020' reason for change: Data Entry Error	Pamela Fidler (b) (4)	27 Oct 2020 15:22:08
User opened query 'Per CDM: Condition start date = UN UNK 2020. Per CCGs page 22 only conditions that started before the Informed Consent was signed are to be reported on the MH eCRF. Please review and confirm the start date is prior to the Informed consent date, else update as per CCGs. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:41:15
User entered 'un UNK 2020'	Katherine Davis (b) (4)	13 Aug 2020 21:49:01

US3012118

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:49:01

US3012118

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:49:01

US3012118

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:49:01

US3012118

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:49:01

US3012118

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	13 Aug 2020 21:49:01

US3012118

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '2020'	System	13 Aug 2020 21:49:01

US3012118

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:49:01

US3012118

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:49:01

US3012118

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Alcoholism, LLT: Alcohol addiction - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:52:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Aug 2020 21:52:17
Data point term sent to Coder	System	13 Aug 2020 21:51:07
User entered 'Alcohol Addiction'	Katherine Davis (b) (4)	13 Aug 2020 21:50:30
	(b) (4)	

US3012118

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:50:30

US3012118

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:50:30

US3012118

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:50:30

US3012118

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:50:30

US3012118

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:50:30

US3012118

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	13 Aug 2020 21:50:30

US3012118

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '2015'	System	13 Aug 2020 21:50:30

US3012118

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:50:30

US3012118

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:50:30

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Aug 2020 22:01:25
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	17 Aug 2020 22:01:25
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	17 Aug 2020 22:01:25
User entered '12 Aug 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	17 Aug 2020 22:01:25
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Aug 2020 21:51:57
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	13 Aug 2020 21:51:57
User entered '11 Aug 2020'	Katherine Davis (b) (4)	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '13:58'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:58'	System	17 Aug 2020 22:01:25
User entered '11 Aug 2020 13:58'	System	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '65.0' in	Katherine Davis (b) (4)	13 Aug 2020 21:51:57
DataPoint set to visible.	(b) (4) System	12 Aug 2020 20:42:50

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '151.6' lb	Katherine Davis (b) (4)	13 Aug 2020 21:51:57
DataPoint set to visible.	(b) (4) System	12 Aug 2020 20:42:50

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
Amendment Manager: User entered '25.28031'	System	16 Sep 2020 23:54:08
User entered '25.3'	System	13 Aug 2020 21:51:57
DataPoint set to visible.	System	12 Aug 2020 20:42:50

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	13 Aug 2020 21:51:57
DataPoint set to visible.	System	12 Aug 2020 20:42:50

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please record "ND" for Temperature. Kindly update accordingly	(b) (4), (b) (6)	13 Oct 2020 04:46:00
' (Site from DM). Query 'Per CDM: Please record "ND" for Temperature. Kindly update accordingly	Jennifer Leyva (b) (4) (b) (4)	12 Oct 2020 15:45:12
' answered with 'updated' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	12 Oct 2020 15:45:08
User opened query 'Per CDM: Please record "ND" for Temperature. Kindly update accordingly	(b) (4), (b) (6)	12 Oct 2020 11:49:41
' (Site from DM). User entered '98.4' F	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	12 Oct 2020 15:45:08
User entered 'Oral (Oral)'	Katherine Davis (b) (4)	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 22:01:25
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Aug 2020 22:01:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 22:01:25
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 21:51:57
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Aug 2020 22:01:25
User entered empty.	System	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 22:01:25
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Aug 2020 22:01:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 22:01:25
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 21:51:57
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Aug 2020 22:01:25
User entered empty.	System	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 22:01:25
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Aug 2020 22:01:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 22:01:25
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 21:51:57
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 22:01:25
User entered empty.	System	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 22:01:25
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	17 Aug 2020 22:01:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 22:01:25
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 21:51:57
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Aug 2020 22:01:25
User entered empty.	System	13 Aug 2020 21:51:57

US3012118

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:25:49

US3012118

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 09:55:55
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		09 Sep 2020 21:36:05
User entered '12 Aug 2020'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:25:49

US3012118

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:26:36

US3012118

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:26:36

US3012118

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:26:36

US3012118

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:26:36

US3012118

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:26:36

US3012118

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:00

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:26:36

US3012118

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:26:36

US3012118

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:00

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	13 Aug 2020 01:26:36

US3012118

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:53:16

US3012118

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:53:16

US3012118

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:53:16

US3012118

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:53:16

US3012118

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

Was FSH sample collected?

Audit	User	Time (GMT)
User closed query 'Per CDM listing review: Was FSH sample collected? Is recorded as "NO", however collection date and collection time is present. Please review and update ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 07:38:26
Query 'Per CDM listing review: Was FSH sample collected? Is recorded as "NO", however collection date and collection time is present. Please review and update ' answered with 'corrected' (Site from DM).	Jennifer Leyva (b) (4)	27 Aug 2020 13:37:05
User opened query 'Per CDM listing review: Was FSH sample collected? Is recorded as "NO", however collection date and collection time is present. Please review and update ' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 13:02:23
User entered 'No (N)'	Katherine Davis (b) (4)	13 Aug 2020 21:53:16

US3012118

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Collection date](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	27 Aug 2020 13:37:00
User entered '12 Aug 2020'	Katherine Davis (b) (4)	13 Aug 2020 21:53:16

US3012118

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Collection time](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Jennifer Leyva (b) (4)	27 Aug 2020 13:37:00
User entered '13:50'	Katherine Davis (b) (4)	13 Aug 2020 21:53:16

US3012118

Folder: Screening

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 13:37:00
User entered '12 Aug 2020 13:50'	System	13 Aug 2020 21:53:16

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

Other

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

No Risk Identified

Audit	User	Time (GMT)
User entered 'I'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

Other

Audit	User	Time (GMT)
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:00

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:01

US3012118

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:23

US3012118

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:23

US3012118

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:23

US3012118

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	13 Aug 2020 21:54:23

US3012118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	12 Aug 2020 20:19:42

US3012118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:00

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:58:24
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:58:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 20:19:42
User entered '103303' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	12 Aug 2020 20:19:42

US3012118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:00

[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) [REDACTED]	12 Aug 2020 20:19:42

US3012118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:00

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)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:44

US3012118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:44

US3012118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:44

US3012118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:00

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:44

US3012118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:00

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:54:44

US3012118

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4)	12 Oct 2020 15:45:36
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:18:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:51:39

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:00

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 04:45:53
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Please update accordingly.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	12 Oct 2020 15:45:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Oct 2020 15:45:27
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:50:21
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4)	12 Oct 2020 15:45:27
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:00

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 04:45:53
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Please update accordingly.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	12 Oct 2020 15:45:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Oct 2020 15:45:27
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:50:21
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4)	12 Oct 2020 15:45:27
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '13:58'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 13:58'	System	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '14'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '77'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:00

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 04:45:53
Query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Please update accordingly.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4)	12 Oct 2020 15:45:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Oct 2020 15:45:27
User opened query 'Per CDM: Subject noted as screened and dosed on same day. However as Per CCG, "ND" should be recorded at Height and Weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:50:21
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:00

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Jennifer Leyva (b) (4)	12 Oct 2020 15:45:27
User entered empty.	Katherine Davis (b) (4)	13 Aug 2020 21:55:50

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 06:45:45
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post vitals to be collected 30 min post not 60 min post ' (Site from System).	Katherine Davis (b) (4)	13 Aug 2020 21:57:24
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		13 Aug 2020 21:56:52
User entered '16:20'	Katherine Davis (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:20'	System	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '14'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '112'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '72'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Aug 2020 21:56:52

US3012118

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:57:43

US3012118

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:57:43

US3012118

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:57:51

US3012118

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:57:51

US3012118

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Test performed](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:57:51

US3012118

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Result](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:57:51

US3012118

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	09 Oct 2020 06:40:55
' (Site from DM). Query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.	Lamar Box (b) (4) (b) (4)	08 Oct 2020 18:42:23
' answered with 'DATA UPDATED' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	Lamar Box (b) (4) (b) (4)	08 Oct 2020 18:42:19
User opened query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	08 Oct 2020 08:33:13
' (Site from DM). User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:57:51

US3012118

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:57:51

US3012118

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:57:51

US3012118

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:57:51

US3012118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:59:13

US3012118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:59:13

US3012118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:59:13

US3012118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 20:59:13

US3012118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:59:13

US3012118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '15:49'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:59:13

US3012118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 15:49'	System	12 Aug 2020 20:59:13

US3012118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4) (b) (4)	12 Aug 2020 20:59:13

US3012118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	12 Aug 2020 20:59:13

US3012118

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 20:59:13

US3012118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:58:48

US3012118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:58:48

US3012118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '14:03'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:58:48

US3012118

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 14:03'	System	13 Aug 2020 21:58:48

US3012118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:59:07

US3012118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Katherine Davis (b) (4)	13 Aug 2020 21:59:07

US3012118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:59:07

US3012118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '15:05'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:59:07

US3012118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12 Aug 2020 15:05'	System	13 Aug 2020 21:59:07

US3012118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Katherine Davis (b) (4)	13 Aug 2020 21:59:07

US3012118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:59:07

US3012118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:59:07

US3012118

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 21:59:07

US3012118

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Aug 2020 21:59:11

US3012118

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 21:59:11

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:20:49', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bc82e82-aff6-4503-a3c2-2aeee6e756ed'	System	12 Aug 2020 21:21:05
User entered 'Yes (Y)'	System	12 Aug 2020 21:21:05

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:20:55', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bc82e82-aff6-4503-a3c2-2aeee6e756ed'	System	12 Aug 2020 21:21:05
User entered '97.8'	System	12 Aug 2020 21:21:05

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:21:00', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bc82e82-aff6-4503-a3c2-2aeee6e756ed'	System	12 Aug 2020 21:21:05
User entered 'No (N)'	System	12 Aug 2020 21:21:05

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:21:03', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bc82e82-aff6-4503-a3c2-2aeee6e756ed'	System	12 Aug 2020 21:21:05
User entered '12 Aug 2020 16:21'	System	12 Aug 2020 21:21:05

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:09'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 18:39'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:40:01', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '44fac0c8-6006-419a-8e8a-b46cb4397c85'	System	13 Aug 2020 00:40:16
User entered 'Yes (Y)'	System	13 Aug 2020 00:40:16

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:40:08', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '44fac0c8-6006-419a-8e8a-b46cb4397c85'	System	13 Aug 2020 00:40:16
User entered '98.3'	System	13 Aug 2020 00:40:16

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:40:10', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '44fac0c8-6006-419a-8e8a-b46cb4397c85'	System	13 Aug 2020 00:40:16
User entered 'No (N)'	System	13 Aug 2020 00:40:16

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:40:12', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '44fac0c8-6006-419a-8e8a-b46cb4397c85'	System	13 Aug 2020 00:40:16
User entered '12 Aug 2020 19:40'	System	13 Aug 2020 00:40:16

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 19:34'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 2'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T18:52:25', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bcaf190-69bb-468e-8429-1e4d24533972'	System	13 Aug 2020 23:52:42
User entered 'Yes (Y)'	System	13 Aug 2020 23:52:42

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T18:52:33', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bcaf190-69bb-468e-8429-1e4d24533972'	System	13 Aug 2020 23:52:42
User entered '99.3'	System	13 Aug 2020 23:52:42

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:00

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T18:52:35', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bcaf190-69bb-468e-8429-1e4d24533972'	System	13 Aug 2020 23:52:42
User entered 'No (N)'	System	13 Aug 2020 23:52:42

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T18:52:38', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bcaf190-69bb-468e-8429-1e4d24533972'	System	13 Aug 2020 23:52:42
User entered '13 Aug 2020 18:52'	System	13 Aug 2020 23:52:42

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 3'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:01:54', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'ed1a9c9a-2001-4e11-93f0-e993af6a3b8a'	System	14 Aug 2020 17:03:05
User entered 'Yes (Y)'	System	14 Aug 2020 17:03:05

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:01:59', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'ed1a9c9a-2001-4e11-93f0-e993af6a3b8a'	System	14 Aug 2020 17:03:05
User entered '98.6'	System	14 Aug 2020 17:03:05

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:00

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:02:08', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'ed1a9c9a-2001-4e11-93f0-e993af6a3b8a'	System	14 Aug 2020 17:03:05
User entered 'No (N)'	System	14 Aug 2020 17:03:05

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:02:11', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'ed1a9c9a-2001-4e11-93f0-e993af6a3b8a'	System	14 Aug 2020 17:03:05
User entered '14 Aug 2020 12:02'	System	14 Aug 2020 17:03:05

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 4'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:15:36', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'fddef9cf-2784-4c93-a892-6917b0980837'	System	16 Aug 2020 02:16:22
User entered 'Yes (Y)'	System	16 Aug 2020 02:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:16:15', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'fddef9cf-2784-4c93-a892-6917b0980837'	System	16 Aug 2020 02:16:22
User entered '97.5'	System	16 Aug 2020 02:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:16:17', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'fddef9cf-2784-4c93-a892-6917b0980837'	System	16 Aug 2020 02:16:22
User entered 'No (N)'	System	16 Aug 2020 02:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:16:19', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'fddef9cf-2784-4c93-a892-6917b0980837'	System	16 Aug 2020 02:16:22
User entered '15 Aug 2020 21:16'	System	16 Aug 2020 02:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 5'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:25:39', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1ad4da90-b204-4260-9561-53d1307730cb'	System	17 Aug 2020 04:25:52
User entered 'Yes (Y)'	System	17 Aug 2020 04:25:52

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:25:45', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1ad4da90-b204-4260-9561-53d1307730cb'	System	17 Aug 2020 04:25:52
User entered '98.7'	System	17 Aug 2020 04:25:52

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:00

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:25:47', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1ad4da90-b204-4260-9561-53d1307730cb'	System	17 Aug 2020 04:25:52
User entered 'No (N)'	System	17 Aug 2020 04:25:52

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:25:50', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1ad4da90-b204-4260-9561-53d1307730cb'	System	17 Aug 2020 04:25:52
User entered '16 Aug 2020 23:25'	System	17 Aug 2020 04:25:52

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 6'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:51:46', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '05e082bb-a522-48d6-90c8-32c3da2a0c34'	System	18 Aug 2020 02:51:56
User entered 'Yes (Y)'	System	18 Aug 2020 02:51:56

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:51:51', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '05e082bb-a522-48d6-90c8-32c3da2a0c34'	System	18 Aug 2020 02:51:56
User entered '97.7'	System	18 Aug 2020 02:51:56

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:00

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:51:53', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '05e082bb-a522-48d6-90c8-32c3da2a0c34'	System	18 Aug 2020 02:51:56
User entered 'No (N)'	System	18 Aug 2020 02:51:56

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:51:55', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '05e082bb-a522-48d6-90c8-32c3da2a0c34'	System	18 Aug 2020 02:51:56
User entered '17 Aug 2020 21:51'	System	18 Aug 2020 02:51:56

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 7'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:00

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:15:47', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '34937b4f-ec04-4878-b708-44117a0b2424'	System	18 Aug 2020 22:15:58
User entered 'Yes (Y)'	System	18 Aug 2020 22:15:58

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:00

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:15:51', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '34937b4f-ec04-4878-b708-44117a0b2424'	System	18 Aug 2020 22:15:58
User entered '97.7'	System	18 Aug 2020 22:15:58

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:00

Was any MEDICATION TAKEN today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:15:53', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '34937b4f-ec04-4878-b708-44117a0b2424'	System	18 Aug 2020 22:15:58
User entered 'No (N)'	System	18 Aug 2020 22:15:58

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:15:56', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '34937b4f-ec04-4878-b708-44117a0b2424'	System	18 Aug 2020 22:15:58
User entered '18 Aug 2020 17:15'	System	18 Aug 2020 22:15:58

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:21:38', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '640dea9e-dfcb-4755-b284-9ca32aa49149'	System	12 Aug 2020 21:21:50
User entered 'None (1)'	System	12 Aug 2020 21:21:50

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:21:40', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '640dea9e-dfcb-4755-b284-9ca32aa49149'	System	12 Aug 2020 21:21:50
User entered 'No (N)'	System	12 Aug 2020 21:21:50

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:21:43', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '640dea9e-dfcb-4755-b284-9ca32aa49149'	System	12 Aug 2020 21:21:50
User entered 'No (N)'	System	12 Aug 2020 21:21:50

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:21:46', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '640dea9e-dfcb-4755-b284-9ca32aa49149'	System	12 Aug 2020 21:21:50
User entered 'None (1)'	System	12 Aug 2020 21:21:50

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:21:48', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '640dea9e-dfcb-4755-b284-9ca32aa49149'	System	12 Aug 2020 21:21:50
User entered '12 Aug 2020 16:21'	System	12 Aug 2020 21:21:50

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:09'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 18:39'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:38:47', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '01b3bdde-5640-4cfa-a03d-c3c945e59522'	System	13 Aug 2020 00:39:00
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 00:39:00

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:38:50', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '01b3bdde-5640-4cfa-a03d-c3c945e59522'	System	13 Aug 2020 00:39:00
User entered 'No (N)'	System	13 Aug 2020 00:39:00

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:38:53', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '01b3bdde-5640-4cfa-a03d-c3c945e59522'	System	13 Aug 2020 00:39:00
User entered 'No (N)'	System	13 Aug 2020 00:39:00

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:38:55', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '01b3bdde-5640-4cfa-a03d-c3c945e59522'	System	13 Aug 2020 00:39:00
User entered 'None (1)'	System	13 Aug 2020 00:39:00

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:38:58', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '01b3bdde-5640-4cfa-a03d-c3c945e59522'	System	13 Aug 2020 00:39:00
User entered '12 Aug 2020 19:38'	System	13 Aug 2020 00:39:00

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 19:34'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 2'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:00

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

Please select one response below

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 07:35:15
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'To be collected at scheduled safety call, per protocol' (Site from DM).	Jennifer Leyva (b) (4)	23 Sep 2020 12:59:30
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 08:31:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T18:59:41', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '421cd36c-a59b-4f49-a75a-3ca249a75dbd'	System	14 Aug 2020 00:00:05
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	14 Aug 2020 00:00:05

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T18:59:44', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '421cd36c-a59b-4f49-a75a-3ca249a75dbd'	System	14 Aug 2020 00:00:05
User entered 'No (N)'	System	14 Aug 2020 00:00:05

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T18:59:51', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '421cd36c-a59b-4f49-a75a-3ca249a75dbd'	System	14 Aug 2020 00:00:05
User entered 'No (N)'	System	14 Aug 2020 00:00:05

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T18:59:59', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '421cd36c-a59b-4f49-a75a-3ca249a75dbd'	System	14 Aug 2020 00:00:05
User entered 'None (1)'	System	14 Aug 2020 00:00:05

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T19:00:01', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '421cd36c-a59b-4f49-a75a-3ca249a75dbd'	System	14 Aug 2020 00:00:05
User entered '13 Aug 2020 19:00'	System	14 Aug 2020 00:00:05

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 3'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:02:18', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '8d87e960-b252-41c1-8e10-b14c5cbbb29f'	System	14 Aug 2020 17:03:23
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 17:03:23

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:02:21', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '8d87e960-b252-41c1-8e10-b14c5cbbb29f'	System	14 Aug 2020 17:03:23
User entered 'No (N)'	System	14 Aug 2020 17:03:23

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:02:27', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '8d87e960-b252-41c1-8e10-b14c5cbbb29f'	System	14 Aug 2020 17:03:23
User entered 'No (N)'	System	14 Aug 2020 17:03:23

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:02:31', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '8d87e960-b252-41c1-8e10-b14c5cbbb29f'	System	14 Aug 2020 17:03:23
User entered 'None (1)'	System	14 Aug 2020 17:03:23

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:02:33', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '8d87e960-b252-41c1-8e10-b14c5cbbb29f' User entered '14 Aug 2020 12:02'	System	14 Aug 2020 17:03:23
	System	14 Aug 2020 17:03:23

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 4'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:16:23', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '7c725af4-410b-4f46-8681-9c8cf0892f1d'	System	16 Aug 2020 02:16:34
User entered 'None (1)'	System	16 Aug 2020 02:16:34

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:16:25', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '7c725af4-410b-4f46-8681-9c8cf0892f1d'	System	16 Aug 2020 02:16:34
User entered 'No (N)'	System	16 Aug 2020 02:16:34

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:16:28', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '7c725af4-410b-4f46-8681-9c8cf0892f1d'	System	16 Aug 2020 02:16:34
User entered 'No (N)'	System	16 Aug 2020 02:16:34

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:16:29', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '7c725af4-410b-4f46-8681-9c8cf0892f1d'	System	16 Aug 2020 02:16:34
User entered 'None (1)'	System	16 Aug 2020 02:16:34

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:16:31', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '7c725af4-410b-4f46-8681-9c8cf0892f1d' User entered '15 Aug 2020 21:16'	System	16 Aug 2020 02:16:34

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 5'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:25:54', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6ba371b3-2082-451b-abdb-b2921cd37d54'	System	17 Aug 2020 04:26:06
User entered 'None (1)'	System	17 Aug 2020 04:26:06

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:25:56', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6ba371b3-2082-451b-abdb-b2921cd37d54'	System	17 Aug 2020 04:26:06
User entered 'No (N)'	System	17 Aug 2020 04:26:06

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:25:58', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6ba371b3-2082-451b-abdb-b2921cd37d54'	System	17 Aug 2020 04:26:06
User entered 'No (N)'	System	17 Aug 2020 04:26:06

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:26:00', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6ba371b3-2082-451b-abdb-b2921cd37d54'	System	17 Aug 2020 04:26:06
User entered 'None (1)'	System	17 Aug 2020 04:26:06

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:26:03', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6ba371b3-2082-451b-abdb-b2921cd37d54'	System	17 Aug 2020 04:26:06
User entered '16 Aug 2020 23:26'	System	17 Aug 2020 04:26:06

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 6'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:16', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '141cc295-472a-43d2-bef2-ac83eed713d8'	System	18 Aug 2020 02:53:27
User entered 'None (1)'	System	18 Aug 2020 02:53:27

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:18', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '141cc295-472a-43d2-bef2-ac83eed713d8'	System	18 Aug 2020 02:53:27
User entered 'No (N)'	System	18 Aug 2020 02:53:27

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:20', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '141cc295-472a-43d2-bef2-ac83eed713d8'	System	18 Aug 2020 02:53:27
User entered 'No (N)'	System	18 Aug 2020 02:53:27

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:23', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '141cc295-472a-43d2-bef2-ac83eed713d8'	System	18 Aug 2020 02:53:27
User entered 'None (1)'	System	18 Aug 2020 02:53:27

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:25', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '141cc295-472a-43d2-bef2-ac83eed713d8'	System	18 Aug 2020 02:53:27
User entered '17 Aug 2020 21:53'	System	18 Aug 2020 02:53:27

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 7'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:15:59', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '004acc1a-77b8-4680-a7c2-1d71d4b49653'	System	18 Aug 2020 22:16:06
User entered 'None (1)'	System	18 Aug 2020 22:16:06

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:01', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '004acc1a-77b8-4680-a7c2-1d71d4b49653'	System	18 Aug 2020 22:16:06
User entered 'No (N)'	System	18 Aug 2020 22:16:06

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:02', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '004acc1a-77b8-4680-a7c2-1d71d4b49653'	System	18 Aug 2020 22:16:06
User entered 'No (N)'	System	18 Aug 2020 22:16:06

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:00

[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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:03', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '004acc1a-77b8-4680-a7c2-1d71d4b49653'	System	18 Aug 2020 22:16:06
User entered 'None (1)'	System	18 Aug 2020 22:16:06

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:05', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '004acc1a-77b8-4680-a7c2-1d71d4b49653'	System	18 Aug 2020 22:16:06
User entered '18 Aug 2020 17:16'	System	18 Aug 2020 22:16:06

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:21:54', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'de123006-4393-4c7b-b41e-fc6e5cffcd8d'	System	12 Aug 2020 21:22:21
User entered 'None (0)'	System	12 Aug 2020 21:22:21

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:21:57', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'de123006-4393-4c7b-b41e-fc6e5cffcd8d'	System	12 Aug 2020 21:22:21
User entered 'None (0)'	System	12 Aug 2020 21:22:21

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:22:01', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'de123006-4393-4c7b-b41e-fc6e5cffcd8d'	System	12 Aug 2020 21:22:21
User entered 'None (0)'	System	12 Aug 2020 21:22:21

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:22:03', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'de123006-4393-4c7b-b41e-fc6e5cffcd8d'	System	12 Aug 2020 21:22:21
User entered 'None (0)'	System	12 Aug 2020 21:22:21

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:22:05', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'de123006-4393-4c7b-b41e-fc6e5cffcd8d'	System	12 Aug 2020 21:22:21
User entered 'None (0)'	System	12 Aug 2020 21:22:21

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:22:07', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'de123006-4393-4c7b-b41e-fc6e5cffcd8d'	System	12 Aug 2020 21:22:21
User entered 'None (0)'	System	12 Aug 2020 21:22:21

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:22:14', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'de123006-4393-4c7b-b41e-fc6e5cffcd8d'	System	12 Aug 2020 21:22:21
User entered 'No (N)'	System	12 Aug 2020 21:22:21

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T16:22:16', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'de123006-4393-4c7b-b41e-fc6e5cffcd8d'	System	12 Aug 2020 21:22:21
User entered '12 Aug 2020 16:22'	System	12 Aug 2020 21:22:21

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 16:09'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 18:39'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:39:12', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'f60803fe-98c2-4883-ab0b-dcb37ac2e157'	System	13 Aug 2020 00:39:35
User entered 'No interference with activity (1)'	System	13 Aug 2020 00:39:35

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:39:08', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'f60803fe-98c2-4883-ab0b-dcb37ac2e157'	System	13 Aug 2020 00:39:35
User entered 'None (0)'	System	13 Aug 2020 00:39:35

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:39:15', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'f60803fe-98c2-4883-ab0b-dcb37ac2e157'	System	13 Aug 2020 00:39:35
User entered 'None (0)'	System	13 Aug 2020 00:39:35

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:39:17', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'f60803fe-98c2-4883-ab0b-dcb37ac2e157'	System	13 Aug 2020 00:39:35
User entered 'None (0)'	System	13 Aug 2020 00:39:35

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:39:21', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'f60803fe-98c2-4883-ab0b-dcb37ac2e157'	System	13 Aug 2020 00:39:35
User entered 'None (0)'	System	13 Aug 2020 00:39:35

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:39:24', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'f60803fe-98c2-4883-ab0b-dcb37ac2e157'	System	13 Aug 2020 00:39:35
User entered 'None (0)'	System	13 Aug 2020 00:39:35

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:39:30', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'f60803fe-98c2-4883-ab0b-dcb37ac2e157'	System	13 Aug 2020 00:39:35
User entered 'No (N)'	System	13 Aug 2020 00:39:35

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-12T19:39:31', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'f60803fe-98c2-4883-ab0b-dcb37ac2e157'	System	13 Aug 2020 00:39:35
User entered '12 Aug 2020 19:39'	System	13 Aug 2020 00:39:35

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 19:34'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 2'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T19:00:07', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '86603443-55b9-4855-a1da-e54c7f593d8a'	System	14 Aug 2020 00:00:32
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	14 Aug 2020 00:00:32

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T19:00:10', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '86603443-55b9-4855-a1da-e54c7f593d8a'	System	14 Aug 2020 00:00:32
User entered 'No interference with activity (1)'	System	14 Aug 2020 00:00:32

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T19:00:15', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '86603443-55b9-4855-a1da-e54c7f593d8a'	System	14 Aug 2020 00:00:32
User entered 'No interference with activity (1)'	System	14 Aug 2020 00:00:32

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T19:00:18', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '86603443-55b9-4855-a1da-e54c7f593d8a'	System	14 Aug 2020 00:00:32
User entered 'No interference with activity (1)'	System	14 Aug 2020 00:00:32

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T19:00:20', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '86603443-55b9-4855-a1da-e54c7f593d8a'	System	14 Aug 2020 00:00:32
User entered 'None (0)'	System	14 Aug 2020 00:00:32

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T19:00:23', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '86603443-55b9-4855-a1da-e54c7f593d8a'	System	14 Aug 2020 00:00:32
User entered 'None (0)'	System	14 Aug 2020 00:00:32

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T19:00:28', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '86603443-55b9-4855-a1da-e54c7f593d8a'	System	14 Aug 2020 00:00:32
User entered 'No (N)'	System	14 Aug 2020 00:00:32

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-13T19:00:30', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '86603443-55b9-4855-a1da-e54c7f593d8a'	System	14 Aug 2020 00:00:32
User entered '13 Aug 2020 19:00'	System	14 Aug 2020 00:00:32

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 3'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:02:45', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '76775fb2-2511-4a4d-8b21-4eed86dc53c5'	System	14 Aug 2020 17:03:52
User entered 'None (0)'	System	14 Aug 2020 17:03:52

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:02:56', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '76775fb2-2511-4a4d-8b21-4eed86dc53c5'	System	14 Aug 2020 17:03:52
User entered 'None (0)'	System	14 Aug 2020 17:03:52

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:02:59', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '76775fb2-2511-4a4d-8b21-4eed86dc53c5'	System	14 Aug 2020 17:03:52
User entered 'None (0)'	System	14 Aug 2020 17:03:52

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:03:05', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '76775fb2-2511-4a4d-8b21-4eed86dc53c5'	System	14 Aug 2020 17:03:52
User entered 'None (0)'	System	14 Aug 2020 17:03:52

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:03:11', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '76775fb2-2511-4a4d-8b21-4eed86dc53c5'	System	14 Aug 2020 17:03:52
User entered 'None (0)'	System	14 Aug 2020 17:03:52

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:03:14', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '76775fb2-2511-4a4d-8b21-4eed86dc53c5'	System	14 Aug 2020 17:03:52
User entered 'None (0)'	System	14 Aug 2020 17:03:52

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:03:17', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '76775fb2-2511-4a4d-8b21-4eed86dc53c5'	System	14 Aug 2020 17:03:52
User entered 'No (N)'	System	14 Aug 2020 17:03:52

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-14T12:03:18', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '76775fb2-2511-4a4d-8b21-4eed86dc53c5'	System	14 Aug 2020 17:03:52
User entered '14 Aug 2020 12:03'	System	14 Aug 2020 17:03:52

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 4'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:16:48', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b41a0902-d332-4200-9b4c-92d8e23a449c'	System	16 Aug 2020 02:33:34
User entered 'No interference with activity (1)'	System	16 Aug 2020 02:33:34

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:33:22', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b41a0902-d332-4200-9b4c-92d8e23a449c'	System	16 Aug 2020 02:33:34
User entered 'None (0)'	System	16 Aug 2020 02:33:34

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:33:23', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b41a0902-d332-4200-9b4c-92d8e23a449c'	System	16 Aug 2020 02:33:34
User entered 'None (0)'	System	16 Aug 2020 02:33:34

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:33:25', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b41a0902-d332-4200-9b4c-92d8e23a449c'	System	16 Aug 2020 02:33:34
User entered 'None (0)'	System	16 Aug 2020 02:33:34

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:33:26', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b41a0902-d332-4200-9b4c-92d8e23a449c'	System	16 Aug 2020 02:33:34
User entered 'None (0)'	System	16 Aug 2020 02:33:34

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:33:28', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b41a0902-d332-4200-9b4c-92d8e23a449c'	System	16 Aug 2020 02:33:34
User entered 'None (0)'	System	16 Aug 2020 02:33:34

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:33:30', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b41a0902-d332-4200-9b4c-92d8e23a449c'	System	16 Aug 2020 02:33:34
User entered 'No (N)'	System	16 Aug 2020 02:33:34

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-15T21:33:32', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b41a0902-d332-4200-9b4c-92d8e23a449c'	System	16 Aug 2020 02:33:34
User entered '15 Aug 2020 21:33'	System	16 Aug 2020 02:33:34

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 5'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:26:07', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b8285ca4-0643-4ce3-915e-0e469281e5c0'	System	17 Aug 2020 04:26:28
User entered 'None (0)'	System	17 Aug 2020 04:26:28

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:26:10', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b8285ca4-0643-4ce3-915e-0e469281e5c0'	System	17 Aug 2020 04:26:28
User entered 'No interference with activity (1)'	System	17 Aug 2020 04:26:28

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:26:13', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b8285ca4-0643-4ce3-915e-0e469281e5c0'	System	17 Aug 2020 04:26:28
User entered 'None (0)'	System	17 Aug 2020 04:26:28

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:26:16', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b8285ca4-0643-4ce3-915e-0e469281e5c0'	System	17 Aug 2020 04:26:28
User entered 'None (0)'	System	17 Aug 2020 04:26:28

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:26:20', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b8285ca4-0643-4ce3-915e-0e469281e5c0'	System	17 Aug 2020 04:26:28
User entered 'None (0)'	System	17 Aug 2020 04:26:28

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:26:22', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b8285ca4-0643-4ce3-915e-0e469281e5c0'	System	17 Aug 2020 04:26:28
User entered 'None (0)'	System	17 Aug 2020 04:26:28

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:26:24', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b8285ca4-0643-4ce3-915e-0e469281e5c0'	System	17 Aug 2020 04:26:28
User entered 'No (N)'	System	17 Aug 2020 04:26:28

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-16T23:26:26', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'b8285ca4-0643-4ce3-915e-0e469281e5c0'	System	17 Aug 2020 04:26:28
User entered '16 Aug 2020 23:26'	System	17 Aug 2020 04:26:28

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 6'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:31', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '36f67c78-854b-495d-9408-b30cc2204a0d'	System	18 Aug 2020 02:53:51
User entered 'No interference with activity (1)'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:33', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '36f67c78-854b-495d-9408-b30cc2204a0d'	System	18 Aug 2020 02:53:51
User entered 'None (0)'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:36', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '36f67c78-854b-495d-9408-b30cc2204a0d'	System	18 Aug 2020 02:53:51
User entered 'None (0)'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:37', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '36f67c78-854b-495d-9408-b30cc2204a0d'	System	18 Aug 2020 02:53:51
User entered 'None (0)'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:38', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '36f67c78-854b-495d-9408-b30cc2204a0d'	System	18 Aug 2020 02:53:51
User entered 'None (0)'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:40', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '36f67c78-854b-495d-9408-b30cc2204a0d'	System	18 Aug 2020 02:53:51
User entered 'None (0)'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:42', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '36f67c78-854b-495d-9408-b30cc2204a0d'	System	18 Aug 2020 02:53:51
User entered 'No (N)'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-17T21:53:49', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '36f67c78-854b-495d-9408-b30cc2204a0d' User entered '17 Aug 2020 21:53'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 7'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:09', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1319d591-71df-42d4-878d-650326a40f85'	System	18 Aug 2020 22:16:22
User entered 'No interference with activity (1)'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:10', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1319d591-71df-42d4-878d-650326a40f85'	System	18 Aug 2020 22:16:22
User entered 'None (0)'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:13', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1319d591-71df-42d4-878d-650326a40f85'	System	18 Aug 2020 22:16:22
User entered 'No interference with activity (1)'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:14', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1319d591-71df-42d4-878d-650326a40f85'	System	18 Aug 2020 22:16:22
User entered 'None (0)'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:15', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1319d591-71df-42d4-878d-650326a40f85'	System	18 Aug 2020 22:16:22
User entered 'None (0)'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:16', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1319d591-71df-42d4-878d-650326a40f85'	System	18 Aug 2020 22:16:22
User entered 'None (0)'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:18', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1319d591-71df-42d4-878d-650326a40f85'	System	18 Aug 2020 22:16:22
User entered 'No (N)'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-18T17:16:20', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '1319d591-71df-42d4-878d-650326a40f85'	System	18 Aug 2020 22:16:22
User entered '18 Aug 2020 17:16'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 02:53:51
User entered 'Day 8'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 08:43:00

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-19T23:52:56', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '0d116cc6-eb2b-4259-adaa-94e2713435af'	System	20 Aug 2020 04:53:03
User entered 'None (0)'	System	20 Aug 2020 04:53:03

US3012118

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 08:43:00

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-19T23:52:59', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '0d116cc6-eb2b-4259-adaa-94e2713435af' User entered '19 Aug 2020 23:52'	System	20 Aug 2020 04:53:03
	System	20 Aug 2020 04:53:03

US3012118

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 22:16:22
User entered 'Day 8'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 08:43:00

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-19T23:53:03', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '94de54c8-0448-46cd-bd95-f2ab2059a13c'	System	20 Aug 2020 04:53:08
User entered 'None (0)'	System	20 Aug 2020 04:53:08

US3012118

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 08:43:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-19T23:53:05', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '94de54c8-0448-46cd-bd95-f2ab2059a13c'	System	20 Aug 2020 04:53:08
User entered '19 Aug 2020 23:53'	System	20 Aug 2020 04:53:08

US3012118

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 22:16:22

US3012118

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Aug 2020 02:53:51
User entered 'Day 8'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 08:43:00

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 (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-19T23:53:08', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'f99f292f-38d1-434a-8ba7-dcc6bbea08ce'	System	20 Aug 2020 04:53:14
User entered 'No (N)'	System	20 Aug 2020 04:53:14

US3012118

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 08:43:00

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-08-19T23:53:11', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'f99f292f-38d1-434a-8ba7-dcc6bbea08ce'	System	20 Aug 2020 04:53:14
User entered '19 Aug 2020 23:53'	System	20 Aug 2020 04:53:14

US3012118

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 08:43:00

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 02:53:51

US3012118

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 08:43:00

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 02:53:51

US3012118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	25 Aug 2020 20:45:33

US3012118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 07:24:24
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct.' (Site from System).	Tambra Dora (b) (4)	25 Aug 2020 20:45:48
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Aug 2020 20:45:33
User entered '25 Aug 2020'	Tambra Dora (b) (4)	25 Aug 2020 20:45:33

US3012118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	25 Aug 2020 20:45:33

US3012118

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	25 Aug 2020 20:45:33

US3012118

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	25 Aug 2020 20:45:56

US3012118

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Aug 2020 20:45:56

US3012118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	31 Aug 2020 13:16:58

US3012118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 10:01:57
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date is correct as entered ' (Site from System).	Tambra Dora (b) (4)	01 Sep 2020 15:01:55
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Sep 2020 15:01:37
User entered '1 Sep 2020' reason for change: New Information	Tambra Dora (b) (4)	01 Sep 2020 15:01:37
User entered '27 Aug 2020'	Tambra Dora (b) (4)	31 Aug 2020 13:16:58

US3012118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 15:01:37
User entered 'Contact Not Made (CONTACT NOT MADE)'	Tambra Dora (b) (4) (b) (4)	31 Aug 2020 13:16:58

US3012118

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty; reason for change New Information	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 15:01:37
User entered 'site attempted 3 times to contact pt.'	Tambra Dora (b) (4) (b) (4)	31 Aug 2020 13:16:58

US3012118

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	31 Aug 2020 13:17:04

US3012118

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Aug 2020 13:17:04

US3012118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:35:36

US3012118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 08:44:23
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Jennifer Leyva (b) (4)	09 Sep 2020 21:35:44
answered with 'correct as entered' (Site from System).	(b) (4)	
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Sep 2020 21:35:36
User entered '08 Sep 2020'	Jennifer Leyva (b) (4)	09 Sep 2020 21:35:36
	(b) (4)	

US3012118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:35:36

US3012118

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'Pt did not respond or call back'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:35:36

US3012118

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:35:47

US3012118

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 21:35:47

US3012118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:05

US3012118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:05

US3012118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:05

US3012118

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	09 Sep 2020 21:36:05

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12:57'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:57'	System	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '128'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '83'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Sep 2020 21:36:27

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:36:34

US3012118

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:45

US3012118

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:36:45

US3012118

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:18

US3012118

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:18

US3012118

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Test performed](#)

Audit	User	Time (GMT)
User entered 'Urine (URINE)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:18

US3012118

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Result](#)

Audit	User	Time (GMT)
User entered 'Negative (NEGATIVE)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:18

US3012118

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

Was FSH sample collected?

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:18

US3012118

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Collection date](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:18

US3012118

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

[Collection time](#)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:18

US3012118

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:37:18

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:28

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

If No, reason not given

Audit	User	Time (GMT)
User closed query 'Per CDM : The reason for study treatment not given is Confirmed Covid 19, but the Covid assessment form is not completed. Kindly clarify and update Covid assessment form and dosing discontinuation form accordingly. Thanks ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 08:47:07
Query 'Per CDM : The reason for study treatment not given is Confirmed Covid 19, but the Covid assessment form is not completed. Kindly clarify and update Covid assessment form and dosing discontinuation form accordingly. Thanks ' answered with 'Subject tested positive at V1, was not symptomatic. ' (Site from DM).	Jennifer Leyva (b) (4)	09 Nov 2020 13:18:25
User opened query 'Per CDM : The reason for study treatment not given is Confirmed Covid 19, but the Covid assessment form is not completed. Kindly clarify and update Covid assessment form and dosing discontinuation form accordingly. Thanks ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:02:09
User entered 'Confirmed COVID-19 (COVID)'	Jennifer Leyva (b) (4)	09 Sep 2020 21:37:28

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:28

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:37:28

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:28

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:28

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:37:28

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:28

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:37:28

US3012118

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:37:28

US3012118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:36

US3012118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:36

US3012118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:37'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:36

US3012118

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '09 Sep 2020 13:37'	System	09 Sep 2020 21:37:36

US3012118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '09 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:48

US3012118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:48

US3012118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:48

US3012118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:27'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:48

US3012118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '09 Sep 2020 13:27'	System	09 Sep 2020 21:37:48

US3012118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:00

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:48

US3012118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:48

US3012118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:00

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:48

US3012118

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 21:37:48

US3012118

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 21:37:51

US3012118

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 21:37:51

US3012118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	17 Sep 2020 22:27:13

US3012118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Katherine Davis (b) (4) (b) (4)	17 Sep 2020 22:27:13

US3012118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Katherine Davis (b) (4) (b) (4)	17 Sep 2020 22:27:13

US3012118

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Katherine Davis (b) (4) (b) (4)	17 Sep 2020 22:27:13

US3012118

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	17 Sep 2020 22:27:19

US3012118

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 22:27:19

US3012118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	24 Sep 2020 22:33:54

US3012118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '24 Sep 2020'	Tambra Dora (b) (4) (b) (4)	24 Sep 2020 22:33:54

US3012118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	24 Sep 2020 22:33:54

US3012118

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	24 Sep 2020 22:33:54

US3012118

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	24 Sep 2020 22:33:57

US3012118

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 22:33:57

US3012118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	30 Sep 2020 17:48:57

US3012118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Tambra Dora (b) (4) (b) (4)	30 Sep 2020 17:48:57

US3012118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	30 Sep 2020 17:48:57

US3012118

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	30 Sep 2020 17:48:57

US3012118

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	30 Sep 2020 17:49:01

US3012118

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 17:49:01

US3012118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 21:58:19

US3012118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 21:58:19

US3012118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Oct 2020 21:58:19

US3012118

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:00

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	08 Oct 2020 21:58:19

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '09:00'	(b) (4), (b) (6)	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '7 Oct 2020 09:00'	System	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	(b) (4), (b) (6)	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '104'	(b) (4), (b) (6)	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:00

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 22:00:15

US3012118

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 22:00:59

US3012118

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:00

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:00:59

US3012118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:01:33

US3012118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 22:01:33

US3012118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '09:10'	(b) (4), (b) (6)	08 Oct 2020 22:01:33

US3012118

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '7 Oct 2020 09:10'	System	08 Oct 2020 22:01:33

US3012118

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:01:41

US3012118

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Oct 2020 22:01:41

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 64'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-10-12T12:34:40', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'c70308fa-483d-474a-b238-b615340a9d24'	System	12 Oct 2020 17:34:50
User entered 'No (N)'	System	12 Oct 2020 17:34:50

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-10-12T12:34:44', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'c70308fa-483d-474a-b238-b615340a9d24'	System	12 Oct 2020 17:34:50
User entered 'No (N)'	System	12 Oct 2020 17:34:50

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-10-12T12:34:47', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'c70308fa-483d-474a-b238-b615340a9d24' User entered '12 Oct 2020 12:34:47'	System	12 Oct 2020 17:34:50
	System	12 Oct 2020 17:34:50

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 71'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-10-19T00:01:13', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bf97ddd-c974-406d-beee-acfcbeffce07'	System	19 Oct 2020 05:01:27
User entered 'No (N)'	System	19 Oct 2020 05:01:27

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-10-19T00:01:19', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bf97ddd-c974-406d-beee-acfcbeffce07'	System	19 Oct 2020 05:01:27
User entered 'No (N)'	System	19 Oct 2020 05:01:27

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-10-19T00:01:22', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '6bf97ddd-c974-406d-beee-acfcbeffce07' User entered '19 Oct 2020 00:01:22'	System	19 Oct 2020 05:01:27
	System	19 Oct 2020 05:01:27

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 78'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-10-28T12:15:12', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'ec34599a-be5b-4ca3-b621-dfc646c0d0bd' User entered 'No (N)'	System	28 Oct 2020 17:15:36
	System	28 Oct 2020 17:15:36

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-10-28T12:15:14', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'ec34599a-be5b-4ca3-b621-dfc646c0d0bd' User entered 'No (N)'	System	28 Oct 2020 17:15:36

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-10-28T12:15:28', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'ec34599a-be5b-4ca3-b621-dfc646c0d0bd' User entered '28 Oct 2020 12:15:28'	System	28 Oct 2020 17:15:36
	System	28 Oct 2020 17:15:36

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 92'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-11-09T18:39:23', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '993c783c-1049-4707-aaa1-51e6c590d873'	System	10 Nov 2020 00:39:37
User entered 'No (N)'	System	10 Nov 2020 00:39:37

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-11-09T18:39:26', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '993c783c-1049-4707-aaa1-51e6c590d873'	System	10 Nov 2020 00:39:37
User entered 'No (N)'	System	10 Nov 2020 00:39:37

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-11-09T18:39:29', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: '993c783c-1049-4707-aaa1-51e6c590d873' User entered '09 Nov 2020 18:39:29'	System	10 Nov 2020 00:39:37
	System	10 Nov 2020 00:39:37

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered 'Day 99'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-11-18T13:20:53', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'c75b413b-d477-44ed-94b4-37f00f50825d' User entered 'No (N)'	System	18 Nov 2020 19:21:02
	System	18 Nov 2020 19:21:02

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-11-18T13:20:55', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'c75b413b-d477-44ed-94b4-37f00f50825d' User entered 'No (N)'	System	18 Nov 2020 19:21:02

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D41897CE-3EC5-41CF-BD70-35D3DA6FEC65)', Time: '2020-11-18T13:20:57', User OID: 'PatientReportedOutcome (US3012118)', ODM File OID: 'c75b413b-d477-44ed-94b4-37f00f50825d' User entered '18 Nov 2020 13:20:57'	System	18 Nov 2020 19:21:02
	System	18 Nov 2020 19:21:02

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 20:59:13

US3012118

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	12 Aug 2020 20:59:13
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 20:59:13

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '09 Oct 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '13 Oct 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '16 Oct 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '20 Oct 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:19:57

US3012118

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:00

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:19:57
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:19:57

US3012118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	04 Nov 2020 18:14:38

US3012118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '04 Nov 2020'	Pamela Fidler (b) (4)	04 Nov 2020 18:14:38

US3012118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Pamela Fidler (b) (4)	04 Nov 2020 18:14:38

US3012118

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:00

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Pamela Fidler (b) (4)	04 Nov 2020 18:14:38

US3012118

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Pamela Fidler (b) (4)	04 Nov 2020 18:14:46

US3012118

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:00

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 18:14:46

US3012118

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:43:00

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:08:54
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	17 Aug 2020 22:22:34

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 17:59:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 17:59:49
Data point term sent to Coder	System	26 Aug 2020 18:11:41
User entered 'intermittent headaches'	Tambra Dora (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '12 Aug 2020'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query "'Per CDM: Site response indicates Start-time is Unknown, however, per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.'" (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:53:37
Query "'Per CDM: Site response indicates Start-time is Unknown, however, per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.'" answered with 'Unknown, not reported. No data to enter.' (Site from DM).	Jennifer Leyva (b) (4)	27 Aug 2020 13:42:32
User opened query "'Per CDM: Site response indicates Start-time is Unknown, however, per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.'" (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 08:32:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 08:32:36
Query 'Data is required. Please provide.' answered with 'unknown ' (Site from System).	Tambra Dora (b) (4)	26 Aug 2020 18:11:20
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:11:04
User entered empty.	Tambra Dora (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 08:32:51
Query 'Data is required. Please provide.' answered with 'unknown ' (Site from System).	Tambra Dora (b) (4)	26 Aug 2020 18:11:28
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	26 Aug 2020 18:11:04
User entered empty.	System	26 Aug 2020 18:11:04
	Tambra Dora (b) (4)	26 Aug 2020 18:11:04
	(b) (4)	

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[None](#)

Audit	User	Time (GMT)
User entered '1'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Aug 2020 18:11:04

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol (i.e., Lasting for more than 7 days post injection). Please review if recorded event meets criteria (i.e., eDiary MUSCLE ACHE Day 8 = NONE). Please review and confirm if MUSCLE ACHE is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise, confirm that this symptom is present at DAY 8 or confirm this is unsolicited event per investigator. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:50:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 14:35:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	20 Oct 2020 14:35:36
Data point term sent to Coder	System	20 Oct 2020 14:34:28
Query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol (i.e., Lasting for more than 7 days post injection). Please review if recorded event meets criteria (i.e., eDiary MUSCLE ACHE Day 8 = NONE). Please review and confirm if MUSCLE ACHE is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise, confirm that this symptom is present at DAY 8 or confirm this is unsolicited event per investigator. ' answered with 'AE term and date corrected to reflect solicited symptom reported on Day 7 of diary, reported per protocol for end date capture' (Site from DM).	Jennifer Leyva (b) (4)	20 Oct 2020 14:34:17
Coding entries removed.	Jennifer Leyva (b) (4)	20 Oct 2020 14:33:51
User entered 'MUSCLE ACHES ALL OVER BODY' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Oct 2020 14:33:51

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol (i.e., Lasting for more than 7 days post injection). Please review if recorded event meets criteria (i.e., eDiary MUSCLE ACHE Day 8 = NONE). Please review and confirm if MUSCLE ACHE is present at Day 8. Else, consider deleting event as this has been captured in Diary Data. Otherwise, confirm that this symptom is present at DAY 8 or confirm this is unsolicited event per investigator. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:01:04
User closed query 'Per DM CLR: Please review and update AE term to reflect specific body location of MUSCLE ACHES (e.g. Generalized, Back, Left Thigh, etc.). Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 11:10:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Generalized muscle aches - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:35:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:35:21
Data point term sent to Coder	System	28 Sep 2020 19:13:15
Query 'Per DM CLR: Please review and update AE term to reflect specific body location of MUSCLE ACHES (e.g. Generalized, Back, Left Thigh, etc.). Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'Updated to reflect Solicited SYmptom verbiage' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	28 Sep 2020 19:12:38
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	28 Sep 2020 19:12:22
User entered 'INTERMITTENT MUSCLE ACHES ALL OVER BODY' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	28 Sep 2020 19:12:22
User opened query 'Per DM CLR: Please review and update AE term to reflect specific body location of MUSCLE ACHES (e.g. Generalized, Back, Left Thigh, etc.). Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:16:27

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 21:35:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 21:35:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:48:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Aug 2020 20:48:51
Data point term sent to Coder	System	26 Aug 2020 18:13:50
User entered 'intermittent muscle aches'	Tambra Dora (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the start date of this solicited event and please note, per subject's Diary record, Muscle Aches was initially noted on 13 Aug 2020. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 08:30:02
Query 'Per DM CLR: Please review the start date of this solicited event and please note, per subject's Diary record, Muscle Aches was initially noted on 13 Aug 2020. Please review and update accordingly. Otherwise, clarify.' answered with 'Updated' (Site from DM).	Pamela Fidler (b) (4)	23 Nov 2020 17:30:56
User entered '13 Aug 2020' reason for change: Data Entry Error	Pamela Fidler (b) (4)	23 Nov 2020 17:30:47
User opened query 'Per DM CLR: Please review the start date of this solicited event and please note, per subject's Diary record, Muscle Aches was initially noted on 13 Aug 2020. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 07:31:30
User entered '18 Aug 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4)	20 Oct 2020 14:33:44
User entered '13 Aug 2020'	Tambra Dora (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 08:30:53
Query 'Data is required. Please provide.' answered with 'Reported time by patient is unknown' (Site from System).	Pamela Fidler (b) (4)	23 Nov 2020 17:31:09
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Nov 2020 17:30:47
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Oct 2020 14:33:44
User closed query "'Per CDM: Site response indicates Start-time is Unknown, however, per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.'" (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 06:54:14
Query "'Per CDM: Site response indicates Start-time is Unknown, however, per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.'" answered with 'Unknown, not reported. No data to enter.' (Site from DM).	Jennifer Leyva (b) (4)	27 Aug 2020 13:42:49
User opened query "'Per CDM: Site response indicates Start-time is Unknown, however, per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed. Enter the start time of the adverse event 24-hour clock format (HH:MM)'. Thank you.'" (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 08:33:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 08:33:05
Query 'Data is required. Please provide.' answered with 'unknown ' (Site from System).	Tambra Dora (b) (4)	26 Aug 2020 18:13:20
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:13:10
User entered empty.	Tambra Dora (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 08:30:59
Query 'Data is required. Please provide.' answered with 'Reported time by patient was unknown' (Site from System).	Pamela Fidler (b) (4)	23 Nov 2020 17:31:24
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Nov 2020 17:30:47
User closed query 'Data is required. Please provide.' (Site from System).	System	20 Oct 2020 14:33:44
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	27 Aug 2020 08:33:20
Query 'Data is required. Please provide.' answered with 'unknown ' (Site from System).	Tambra Dora (b) (4)	26 Aug 2020 18:13:29
User opened query 'Data is required. Please provide.' (Site from System).	System	26 Aug 2020 18:13:10
User entered empty.	Tambra Dora (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[None](#)

Audit	User	Time (GMT)
User entered '1'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Tambra Dora (b) (4) (b) (4)	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 08:43:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Aug 2020 18:13:10

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:17:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 00:17:15
Data point term sent to Coder	System	09 Oct 2020 00:10:03
User entered 'SYNCOPE'	Lamar Box (b) (4)	09 Oct 2020 00:09:22
	(b) (4)	

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 00:09:40
User entered empty; reason for change Data Entry Error	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:40
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	09 Oct 2020 00:09:22
User entered '13:37'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 00:09:40
User entered '9 Sep 2020 13:37'	System	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	09 Oct 2020 00:09:40
User entered empty; reason for change Data Entry Error	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:40
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	09 Oct 2020 00:09:22
User entered '13:38'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 00:09:40
User entered '9 Sep 2020 13:38'	System	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[None](#)

Audit	User	Time (GMT)
User entered '1'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Lamar Box (b) (4) (b) (4)	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 00:09:22

US3012118

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 08:43:00

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Oct 2020 00:09:22

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:43:00

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:07:52

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 00:12:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 00:12:15
Data point term sent to Coder	System	08 Oct 2020 22:10:04
User entered 'LAMOTRIGINE'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'BIPOLAR DISORDER'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 22:09:23

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:12:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Oct 2020 00:12:16
Data point term sent to Coder	System	08 Oct 2020 22:11:06
User entered 'TRAZADONE'	(b) (4), (b) (6) (b) (4)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Indication](#)

Audit	User	Time (GMT)
User entered 'BIPOLAR DISORDER'	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '50'	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

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

Audit	User	Time (GMT)
User entered 'UN Jan 2020'	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:00

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Oct 2020 22:10:48

US3012118

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:43:00

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lamar Box (b) (4) (b) (4)	13 Oct 2020 17:58:26

US3012118

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:00

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	29 Sep 2020 19:01:11

US3012118

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:00

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'Due to SARS-COV-2 (COVID)'	Jennifer Leyva (b) (4) (b) (4)	29 Sep 2020 19:01:11

US3012118

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:00

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	29 Sep 2020 19:01:11