

US3022208 (Prod: Meridian Clinical Research)

Generated By: (b) (6)

Generated On: 26 Nov 2020 08:43:40

All time stamps listed in this document are displayed in GMT

US3022208

Form: Participant Creation

Generated On: 26 Nov 2020 08:43:40

[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 08:43:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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 08:43:40

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 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 08:43:40

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:43:40

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

Condition	HEPATITIS C
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

Condition	BREAST CANCER
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

Condition	MASECTOMY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

Condition	CHRONIC PAIN
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

Condition	CHRONIC CONSTIPTION
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:15
Height (<i>xxx.x</i>)	174 cm
Weight (<i>xxx.x</i>)	97.0 kg
BMI (<i>xxx.x</i>)	32.03858 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 08:43:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 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 08:43:40

Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Is the participant of childbearing potential?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If No, what is the reason?	Surgically sterile <input type="radio"/>
	Post-menopausal <input checked="" type="radio"/>
	Partner medically sterile <input type="radio"/>
	Not reached age of Menarche <input type="radio"/>
	Other <input type="radio"/>
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2016
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	LIVES IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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 08:43:40

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 106521

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 08:43:40

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 08:43:40

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)	20 AUG 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:15
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

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)	20 AUG 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:50
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 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: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

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)	20 AUG 2020
What was the treatment time? (00:00-23:59)	15:13 (24 HR)
Treatment Date and Time (derived)	20 AUG 2020 15:13
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 08:43:40

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	20 AUG 2020
Collection time (<i>00:00-23:59</i>)	14:37 (24 HR)
Collection date and time (derived)	20 AUG 2020 14:37

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:40

Collection date (<i>dd MMM yyyy</i>)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:49	20 AUG 2020 14:49
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

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 08:43:40

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 15:46

PC Open Date & Time

20 AUG 2020 15:33

PC Close Date & Time

20 AUG 2020 18:03

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °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	20 AUG 2020 20:49
PC Open Date & Time	20 AUG 2020 18:58
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:40

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 ☒

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 AUG 2020 20:18

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:40

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:40

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 13:20

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE in °F**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 24 AUG 2020 12:00

PC Close Date & Time 25 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:40

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 25 AUG 2020 12:01

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:40

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 26 AUG 2020 20:09

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

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

20 AUG 2020 15:47

PC Open Date & Time

20 AUG 2020 15:33

PC Close Date & Time

20 AUG 2020 18:03

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

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

20 AUG 2020 20:49

PC Open Date & Time

20 AUG 2020 18:58

PC Close Date & Time

21 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

1

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

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

Yes ☒

No ☐

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

1

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 20:19

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:40

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

23 AUG 2020 13:21

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:40

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

25 AUG 2020 12:02

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:40

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

26 AUG 2020 20:09

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 15:48
PC Open Date & Time	20 AUG 2020 15:33
PC Close Date & Time	20 AUG 2020 18:03

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 20:49
PC Open Date & Time	20 AUG 2020 18:58
PC Close Date & Time	21 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

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 ☒

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 20:20
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

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 ☒

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 13:21
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

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 ☒

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:03
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

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 ☒

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 20:09
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3022208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

Was Contact Attempted?

Yes ☒

No ☐

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

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

Was Contact Attempted?

Yes ☒

No ☐

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

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

Was Contact Attempted?

Yes ☒

No ☐

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

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

Was this visit performed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Visit date (dd MMM yyyy)	
--------------------------	--

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input type="radio"/>

Folder OID	VISIT2
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US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

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	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

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.

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

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? _____

US3022208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:40

Was the sample collected?

Yes ☐

No ☒

Collection date (*dd MMM yyyy*)

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

Collection date and time (derived)

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:40

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3022208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

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.

US3022208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:40

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3022208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

21 OCT 2020 16:08:35

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

27 OCT 2020 20:23:38

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

17 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

05 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

26 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

23 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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="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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

27 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

06 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

20 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 222

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

03 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 327

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

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

No ☐
Yes ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

Patient Cloud Open Date & Time	02 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 MAR 2022 00:01
Patient Cloud Close Date & Time	30 MAR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

Patient Cloud Open Date & Time	23 APR 2022 00:01
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Patient Cloud Close Date & Time	27 APR 2022 23:59
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US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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="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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2022 00:01
Patient Cloud Close Date & Time	31 AUG 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 754

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

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

No ☐

Yes ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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="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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

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

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3022208

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 08:43:40

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"/>

US3022208

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 08:43:40

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 08:43:40

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3022208

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3022208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

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.

US3022208

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 08:43:40

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	SICKD28

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:50 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 14:50
Height (<i>xxx.x</i>)	174 cm
Weight (<i>xxx.x</i>)	98.4 kg
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 08:43:40

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 OCT 2020

US3022208

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:43:40

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

AEID	USA-US051-2020-MRNA-1273-P30 1000003
Adverse event	CONGESTIVE HEART FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	10 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)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	14 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
v6.020 DTW (1102)	315 of 1485

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	DUE TO CONGESTIVE HEART FAILURE IS A NEW DIAGNOSIS.
Narrative	UPDATED SAE WITH MEDIAL RECORDS HAVE BEEN EMAILED OVER. MEDICATION AND PROCEDURE. SAE DUE TO COCAINE ABUSE.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:43:40

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

Yes ☒

No ☐

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

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

	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)		21 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

Name of Medication	HYDROCODONE/ACETAMINOP HEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CHRONIC PAIN
Dose per administration	7.5/325
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN UNK 2014
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

Name of Medication	POLYETHYLENE GLYCOL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	CHRONIC CONSTIPTION
Dose per administration	17
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input checked="" type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

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

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:43:40

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 08:43:40

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
11 SEP 2020	ELECTROCARDIOGRAM	Adverse Event	
11 SEP 2020	ECHOCARDIOGRAM	Adverse Event	

US3022208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:40

Date of dosing discontinuation (dd MMM yyyy)

10 SEP 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

SAE #1

US3022208

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 08:43:40

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 ☐

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:43:40

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/SEP/2020 10:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:43:40

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	05/OCT/2020 09:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:43:40

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	08/OCT/2020 16:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:43:40

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/NOV/2020 20:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:43:40

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	16/NOV/2020 08:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 08:43:40

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/NOV/2020 19:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022208 (Prod: Meridian Clinical Research)

US3022208

Form: Participant Creation

Generated On: 26 Nov 2020 08:43:40

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3022208'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 18:19:42

US3022208

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:01:52

US3022208

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 18:19:43

US3022208

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:01:52

US3022208

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	20 Aug 2020 20:01:52

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 18:19:44

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Age](#)

Audit	User	Time (GMT)
User entered '60'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '60'	System	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[White](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Black](#)

Audit	User	Time (GMT)
User entered 'I'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 08:43:40

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '2020'	System	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 18:19:43

US3022208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 08:43:40

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 08:43:40

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Query 'Please add the medical history per source. Thank you.' answered with 'ADDED' (Site from CRA).	Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 21:54:35
User opened query 'Please add the medical history per source. Thank you.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	10 Nov 2020 17:24:24
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:03:15

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:05:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	20 Aug 2020 20:05:24
Data point term sent to Coder	System	20 Aug 2020 20:04:20
User entered 'post menopausal'	Stella Yoon (b) (4)	20 Aug 2020 20:03:36
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '2016'	System	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

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

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

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 08:43:40

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

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

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:17:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:17:43
Data point term sent to Coder	System	10 Nov 2020 20:16:29
User entered 'hypertension'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '2010'	System	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis C, LLT: Hepatitis C - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:42
Data point term sent to Coder	System	10 Nov 2020 20:16:29
User entered 'Hepatitis C'	Shanice Bennett (b) (4)	10 Nov 2020 20:15:49
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '2014'	System	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:41
Data point term sent to Coder	System	10 Nov 2020 20:16:28
User entered 'Insomnia'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:03
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 1975'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 1975'	System	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '1975'	System	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:32:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:32:40
Data point term sent to Coder	System	10 Nov 2020 20:16:30
User entered 'bipolar disorder'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 1975'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 1975'	System	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '1975'	System	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:48:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:48:29
Data point term sent to Coder	System	10 Nov 2020 20:17:31
User entered 'breast cancer'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '2014'	System	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '2014'	System	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Mastectomy, LLT: Mastectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:53:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:53:45
Data point term sent to Coder	System	10 Nov 2020 20:17:32
User entered 'masectomy'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '2014'	System	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '2014'	System	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

[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)	10 Nov 2020 20:17:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:46
Data point term sent to Coder	System	10 Nov 2020 20:17:33
User entered 'depression'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:11
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 1975'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 1975'	System	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '1975'	System	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Chronic pain - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:45
Data point term sent to Coder	System	10 Nov 2020 20:17:32
User entered 'chronic Pain'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '2014'	System	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation chronic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:01:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:01:46
Data point term sent to Coder	System	10 Nov 2020 20:18:35
User entered 'chronic constipation'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2014'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Jan 2014'	System	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '2014'	System	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '14:15'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:15'	System	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '174' cm	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
DataPoint set to visible.	(b) (4) System	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '97.0' kg	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
DataPoint set to visible.	(b) (4) System	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
Amendment Manager: User entered '32.03858'	System	17 Sep 2020 00:16:37
User entered '32.0'	System	20 Aug 2020 20:04:46
DataPoint set to visible.	System	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	20 Aug 2020 20:04:46
DataPoint set to visible.	System	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 05:34:31
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 17:37:53
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 17:37:46
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for “Not done” and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:49:23
User entered '36.8' C	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:37:46
User entered 'Oral (Oral)'	(b) (4)	
	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:37:46
User entered '96'	(b) (4)	
	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:37:46
User entered '12'	(b) (4)	
	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 17:37:46
User entered '130'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:37:46
User entered '86'	(b) (4)	
	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:04:53

US3022208

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:04:53

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:05:10

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:40

Is the participant of childbearing potential?

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:05:10

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:05:10

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:40

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:05:10

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:05:10

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:40

Date of surgery unknown

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:05:10

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:05:10

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 08:43:40

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:05:10

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'I'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '0'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 08:43:40

[Specify](#)

Audit	User	Time (GMT)
User entered 'lives in a community with ongoing person to person transmission'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:07

US3022208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation Requery2 : Saliva: Thank you for initiating the Illness visit, however please confirm to update the 19Oct2020 sample in the Saliva collection form.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:22:22
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Thank you for your response, however please confirm in the response if a Saliva Sample dated 19OCT2020 was collected for the subject and sent to PPD Central lab as the above dated sample is reported under Convalescence Visit Day 28 in PPD If yes then update the data in the Saliva log or Covid diagnostic form as applicable.. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:22:22
Query 'Per GCL Lab Reconciliation Requery: Saliva: Shanice Bennett Thank you for your response, however please confirm in the response if a Saliva Sample dated 19OCT2020 was collected for the subject and sent to PPD Central lab as the above dated sample is reported under Convalescence Visit Day 28 in PPD If yes then update the data in the Saliva log or Covid diagnostic form as applicable.. ' answered with 'updated' (Site from DM).	(b) (4)	20 Nov 2020 16:37:50
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Thank you for your response, however please confirm in the response if a Saliva Sample dated 19OCT2020 was collected for the subject and sent to PPD Central lab as the above dated sample is reported under Convalescence Visit Day 28 in PPD If yes then update the data in the Saliva log or Covid diagnostic form as applicable.. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:35:53
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:35:53

US3022208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'subject tested positive outside of clinic ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 23:26:40
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	29 Oct 2020 06:29:37
' (Site from DM).		
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:20

US3022208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:20

US3022208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:20

US3022208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	20 Aug 2020 20:06:20

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	20 Aug 2020 18:59:28

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:40

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 05:57:49
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:57:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 18:59:28
User entered '106521' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 18:59:28

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:40

[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]	20 Aug 2020 18:59:28

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:40

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)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:33

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:33

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:33

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:40

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:33

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:40

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:33

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 11:28:43
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 19:11:09
User entered 'No (N)'	Morgan Deal (b) (4)	12 Nov 2020 19:11:04
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 17:22:08
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:48:33

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:40

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:38:08
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 17:51:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	12 Nov 2020 17:51:24
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:19:16
User entered '174' cm	Stella Yoon (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:40

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:51:24
User entered '97.0' kg	(b) (4)	
	Stella Yoon (b) (4)	20 Aug 2020 20:07:55
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:40

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:38:08
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 17:51:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	12 Nov 2020 17:51:24
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:19:16
User entered '174' cm	Stella Yoon (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:40

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:51:24
User entered '97.0' kg	(b) (4)	
	Stella Yoon (b) (4)	20 Aug 2020 20:07:55
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '14:15'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:15'	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '96'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '12'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '86'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:40

Height

Audit	User	Time (GMT)
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:38:08
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 17:51:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	12 Nov 2020 17:51:24
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:19:16
User entered '174' cm	Stella Yoon (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 08:43:40

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:51:24
User entered '97.0' kg	(b) (4)	
	Stella Yoon (b) (4)	20 Aug 2020 20:07:55
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 16:13:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Aug 2020 16:13:10
User entered '15:50' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:13:10
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:07:55
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:50'	System	24 Aug 2020 16:13:10
User entered empty.	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '103'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '14'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '133'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '88'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:08:40

US3022208

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:08:40

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '15:13'	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:13'	System	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:08:58

US3022208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:55:30
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'date 20aug2020 is correct date' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 23:49:53
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:47:24
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 20:08:58

US3022208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:37'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:08:58

US3022208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:37'	System	20 Aug 2020 20:08:58

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Rec: it appears GCL has this as 21AUG2020 Please confirm the date of 20AUG2020 is for Day 1 or clarify' answered with '20aug2020 date is correct' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 23:45:20
User opened query 'Per GCL Lab Rec: it appears GCL has this as 21AUG2020 Please confirm the date of 20AUG2020 is for Day 1 or clarify' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 18:05:33
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:49'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:49'	System	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:14

US3022208

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:09:14

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:46:17', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '99d18617-fb89-493e-a722-64649ad6a6a6'	System	20 Aug 2020 19:46:51
User entered 'Yes (Y)'	System	20 Aug 2020 19:46:51

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:46:27', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '99d18617-fb89-493e-a722-64649ad6a6a6'	System	20 Aug 2020 19:46:51
User entered '97.9'	System	20 Aug 2020 19:46:51

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:46:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '99d18617-fb89-493e-a722-64649ad6a6a6'	System	20 Aug 2020 19:46:51
User entered 'No (N)'	System	20 Aug 2020 19:46:51

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:46:47', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '99d18617-fb89-493e-a722-64649ad6a6a6'	System	20 Aug 2020 19:46:51
User entered '20 Aug 2020 15:46'	System	20 Aug 2020 19:46:51

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:33'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 18:03'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:48:31', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '9c78286a-2f5f-44f8-ab7e-dc754081aa9c'	System	21 Aug 2020 00:49:11
User entered 'Yes (Y)'	System	21 Aug 2020 00:49:11

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:48:50', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '9c78286a-2f5f-44f8-ab7e-dc754081aa9c'	System	21 Aug 2020 00:49:11
User entered '97.3'	System	21 Aug 2020 00:49:11

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:48:58', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '9c78286a-2f5f-44f8-ab7e-dc754081aa9c'	System	21 Aug 2020 00:49:11
User entered 'No (N)'	System	21 Aug 2020 00:49:11

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:08', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '9c78286a-2f5f-44f8-ab7e-dc754081aa9c'	System	21 Aug 2020 00:49:11
User entered '20 Aug 2020 20:49'	System	21 Aug 2020 00:49:11

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 18:58'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 2'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:40

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:17:36', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '929070d5-a993-4b94-9845-ac12e7948b27'	System	22 Aug 2020 00:18:21
User entered 'No (N)'	System	22 Aug 2020 00:18:21

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:17:59', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '929070d5-a993-4b94-9845-ac12e7948b27'	System	22 Aug 2020 00:18:21
User entered 'Yes (Y)'	System	22 Aug 2020 00:18:21

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	28 Aug 2020 04:19:42
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'UPDATED' (Site from System).	Shanice Bennett (b) (4)	27 Aug 2020 21:26:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	22 Aug 2020 00:18:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:18:13', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '929070d5-a993-4b94-9845-ac12e7948b27'	System	22 Aug 2020 00:18:21
User entered '1'	System	22 Aug 2020 00:18:21

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:40

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:18:13', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '929070d5-a993-4b94-9845-ac12e7948b27'	System	22 Aug 2020 00:18:21
User entered '0'	System	22 Aug 2020 00:18:21

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:18:18', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '929070d5-a993-4b94-9845-ac12e7948b27'	System	22 Aug 2020 00:18:21
User entered '21 Aug 2020 20:18'	System	22 Aug 2020 00:18:21

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 3'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 4'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:21', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '618a4611-0923-45a9-9b70-ba697a3d2b78'	System	23 Aug 2020 17:20:44
User entered 'Yes (Y)'	System	23 Aug 2020 17:20:44

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:31', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '618a4611-0923-45a9-9b70-ba697a3d2b78'	System	23 Aug 2020 17:20:44
User entered '97.3'	System	23 Aug 2020 17:20:44

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:36', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '618a4611-0923-45a9-9b70-ba697a3d2b78'	System	23 Aug 2020 17:20:44
User entered 'No (N)'	System	23 Aug 2020 17:20:44

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:40', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '618a4611-0923-45a9-9b70-ba697a3d2b78'	System	23 Aug 2020 17:20:44
User entered '23 Aug 2020 13:20'	System	23 Aug 2020 17:20:44

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 5'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 6'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:01:28', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '48528472-4c23-4401-bb58-29a8f58bb5e4'	System	25 Aug 2020 16:02:13
User entered 'No (N)'	System	25 Aug 2020 16:02:13

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:01:30', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '48528472-4c23-4401-bb58-29a8f58bb5e4'	System	25 Aug 2020 16:02:13
User entered 'No (N)'	System	25 Aug 2020 16:02:13

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:01:46', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '48528472-4c23-4401-bb58-29a8f58bb5e4'	System	25 Aug 2020 16:02:13
User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:02:13

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 7'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:40

Was TEMPERATURE taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:05', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '950060cf-3c29-4aeb-a3af-3a01dcf8c09a'	System	27 Aug 2020 00:09:15
User entered 'No (N)'	System	27 Aug 2020 00:09:15

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:08', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '950060cf-3c29-4aeb-a3af-3a01dcf8c09a'	System	27 Aug 2020 00:09:15
User entered 'No (N)'	System	27 Aug 2020 00:09:15

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:12', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '950060cf-3c29-4aeb-a3af-3a01dcf8c09a'	System	27 Aug 2020 00:09:15
User entered '26 Aug 2020 20:09'	System	27 Aug 2020 00:09:15

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-20T15:46:58', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'f98b8385-08bc-4c04-83f3-4ac2d3e74269'	System	20 Aug 2020 19:47:17
User entered 'None (1)'	System	20 Aug 2020 19:47:17

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:01', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'f98b8385-08bc-4c04-83f3-4ac2d3e74269'	System	20 Aug 2020 19:47:17
User entered 'No (N)'	System	20 Aug 2020 19:47:17

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:04', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'f98b8385-08bc-4c04-83f3-4ac2d3e74269'	System	20 Aug 2020 19:47:17
User entered 'No (N)'	System	20 Aug 2020 19:47:17

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-20T15:47:08', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'f98b8385-08bc-4c04-83f3-4ac2d3e74269'	System	20 Aug 2020 19:47:17
User entered 'None (1)'	System	20 Aug 2020 19:47:17

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:12', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'f98b8385-08bc-4c04-83f3-4ac2d3e74269'	System	20 Aug 2020 19:47:17
User entered '20 Aug 2020 15:47'	System	20 Aug 2020 19:47:17

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:33'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 18:03'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-20T20:49:16', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5f75e82d-b1e7-49b6-b875-301924bcd8a6'	System	21 Aug 2020 00:49:33
User entered 'None (1)'	System	21 Aug 2020 00:49:33

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:20', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5f75e82d-b1e7-49b6-b875-301924bcd8a6'	System	21 Aug 2020 00:49:33
User entered 'No (N)'	System	21 Aug 2020 00:49:33

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:23', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5f75e82d-b1e7-49b6-b875-301924bcd8a6'	System	21 Aug 2020 00:49:33
User entered 'No (N)'	System	21 Aug 2020 00:49:33

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-20T20:49:27', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5f75e82d-b1e7-49b6-b875-301924bcd8a6'	System	21 Aug 2020 00:49:33
User entered 'None (1)'	System	21 Aug 2020 00:49:33

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:30', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5f75e82d-b1e7-49b6-b875-301924bcd8a6'	System	21 Aug 2020 00:49:33
User entered '20 Aug 2020 20:49'	System	21 Aug 2020 00:49:33

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 18:58'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 2'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

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

Please select one response below

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness = 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. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 12:10:22
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness = 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)	09 Sep 2020 09:22:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:18:37', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	System	22 Aug 2020 00:19:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:18:44', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	System	22 Aug 2020 00:19:37
User entered 'Yes (Y)'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:01', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	System	22 Aug 2020 00:19:37
User entered '1'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:07', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	System	22 Aug 2020 00:19:37
User entered 'Yes (Y)'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:19', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	System	22 Aug 2020 00:19:37
User entered '1'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

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

Please select one response below

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = 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)	15 Oct 2020 15:42:12
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = 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 'will add med ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 21:17:28
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = 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)	09 Sep 2020 12:11:51
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness = 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.' canceled (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 12:06:36

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

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

Please select one response below

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness = 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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:30', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	(b) (4), (b) (6)	09 Sep 2020 09:23:57
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	System	22 Aug 2020 00:19:37
User entered '21 Aug 2020 20:19'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 3'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 4'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-23T13:20:49', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '72d89327-2d92-451b-8ad5-935aa50fb9d4'	System	23 Aug 2020 17:21:08
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 17:21:08

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:53', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '72d89327-2d92-451b-8ad5-935aa50fb9d4'	System	23 Aug 2020 17:21:08
User entered 'No (N)'	System	23 Aug 2020 17:21:08

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:57', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '72d89327-2d92-451b-8ad5-935aa50fb9d4'	System	23 Aug 2020 17:21:08
User entered 'No (N)'	System	23 Aug 2020 17:21:08

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:40

[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 (055dec66dc3e364a)', Time: '2020-08-23T13:21:01', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '72d89327-2d92-451b-8ad5-935aa50fb9d4'	System	23 Aug 2020 17:21:08
User entered 'None (1)'	System	23 Aug 2020 17:21:08

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:04', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '72d89327-2d92-451b-8ad5-935aa50fb9d4'	System	23 Aug 2020 17:21:08
User entered '23 Aug 2020 13:21'	System	23 Aug 2020 17:21:08

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 5'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 6'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-25T12:01:55', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5dbda000-515f-45ce-89a9-f6403eec8af6'	System	25 Aug 2020 16:03:13
User entered 'None (1)'	System	25 Aug 2020 16:03:13

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:01:59', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5dbda000-515f-45ce-89a9-f6403eec8af6'	System	25 Aug 2020 16:03:13
User entered 'No (N)'	System	25 Aug 2020 16:03:13

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:17', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5dbda000-515f-45ce-89a9-f6403eec8af6'	System	25 Aug 2020 16:03:13
User entered 'No (N)'	System	25 Aug 2020 16:03:13

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-25T12:02:29', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5dbda000-515f-45ce-89a9-f6403eec8af6'	System	25 Aug 2020 16:03:13
User entered 'None (1)'	System	25 Aug 2020 16:03:13

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5dbda000-515f-45ce-89a9-f6403eec8af6'	System	25 Aug 2020 16:03:13
User entered '25 Aug 2020 12:02'	System	25 Aug 2020 16:03:13

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 7'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-26T20:09:18', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '67d40273-0402-4042-8c35-8cc118c240e5'	System	27 Aug 2020 00:09:34
User entered 'None (1)'	System	27 Aug 2020 00:09:34

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:21', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '67d40273-0402-4042-8c35-8cc118c240e5'	System	27 Aug 2020 00:09:34
User entered 'No (N)'	System	27 Aug 2020 00:09:34

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:23', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '67d40273-0402-4042-8c35-8cc118c240e5'	System	27 Aug 2020 00:09:34
User entered 'No (N)'	System	27 Aug 2020 00:09:34

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-26T20:09:26', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '67d40273-0402-4042-8c35-8cc118c240e5'	System	27 Aug 2020 00:09:34
User entered 'None (1)'	System	27 Aug 2020 00:09:34

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:40

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:29', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '67d40273-0402-4042-8c35-8cc118c240e5'	System	27 Aug 2020 00:09:34
User entered '26 Aug 2020 20:09'	System	27 Aug 2020 00:09:34

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:22', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	System	20 Aug 2020 19:48:37
User entered 'None (0)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:31', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	System	20 Aug 2020 19:48:37
User entered 'None (0)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:35', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	System	20 Aug 2020 19:48:37
User entered 'None (0)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:40', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	System	20 Aug 2020 19:48:37
User entered 'None (0)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:48:17', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	System	20 Aug 2020 19:48:37
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:48:21', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	System	20 Aug 2020 19:48:37
User entered 'None (0)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-20T15:48:28', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	System	20 Aug 2020 19:48:37
User entered 'No (N)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:48:32', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	System	20 Aug 2020 19:48:37
User entered '20 Aug 2020 15:48'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:33'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 18:03'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	System	21 Aug 2020 00:49:56
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:37', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	System	21 Aug 2020 00:49:56
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:40', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	System	21 Aug 2020 00:49:56
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:42', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	System	21 Aug 2020 00:49:56
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:44', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	System	21 Aug 2020 00:49:56
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:47', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	System	21 Aug 2020 00:49:56
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-20T20:49:49', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	System	21 Aug 2020 00:49:56
User entered 'No (N)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:52', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	System	21 Aug 2020 00:49:56
User entered '20 Aug 2020 20:49'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 18:58'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 2'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:40', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	System	22 Aug 2020 00:20:16
User entered 'None (0)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:45', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	System	22 Aug 2020 00:20:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:49', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	System	22 Aug 2020 00:20:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:53', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	System	22 Aug 2020 00:20:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:20:02', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	System	22 Aug 2020 00:20:16
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:20:07', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	System	22 Aug 2020 00:20:16
User entered 'None (0)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-21T20:20:11', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	System	22 Aug 2020 00:20:16
User entered 'No (N)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:20:14', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	System	22 Aug 2020 00:20:16
User entered '21 Aug 2020 20:20'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 3'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 4'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:15', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	System	23 Aug 2020 17:21:50
User entered 'No interference with activity (1)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:20', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	System	23 Aug 2020 17:21:50
User entered 'No interference with activity (1)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:26', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	System	23 Aug 2020 17:21:50
User entered 'Some interference with activity (2)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:30', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	System	23 Aug 2020 17:21:50
User entered 'Some interference with activity (2)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:33', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	System	23 Aug 2020 17:21:50
User entered 'None (0)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:36', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	System	23 Aug 2020 17:21:50
User entered 'None (0)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-23T13:21:41', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	System	23 Aug 2020 17:21:50
User entered 'No (N)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:44', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	System	23 Aug 2020 17:21:50
User entered '23 Aug 2020 13:21'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 5'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 6'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:48', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	System	25 Aug 2020 16:03:44
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:50', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	System	25 Aug 2020 16:03:44
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:53', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	System	25 Aug 2020 16:03:44
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:55', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	System	25 Aug 2020 16:03:44
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:58', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	System	25 Aug 2020 16:03:44
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:03:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	System	25 Aug 2020 16:03:44
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-25T12:03:03', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	System	25 Aug 2020 16:03:44
User entered 'No (N)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:03:06', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	System	25 Aug 2020 16:03:44
User entered '25 Aug 2020 12:03'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 7'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:35', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	System	27 Aug 2020 00:09:59
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:39', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	System	27 Aug 2020 00:09:59
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:41', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	System	27 Aug 2020 00:09:59
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:44', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	System	27 Aug 2020 00:09:59
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:47', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	System	27 Aug 2020 00:09:59
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:49', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	System	27 Aug 2020 00:09:59
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

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 (055dec66dc3e364a)', Time: '2020-08-26T20:09:52', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	System	27 Aug 2020 00:09:59
User entered 'No (N)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:55', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	System	27 Aug 2020 00:09:59
User entered '26 Aug 2020 20:09'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 08:43:40

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:01:53

US3022208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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)	16 Oct 2020 16:19:11
User entered '27 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 17:03:46
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 'this is correct ' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 17:02:31
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	15 Oct 2020 17:01:53
User entered '03 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 17:01:53

US3022208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Oct 2020 17:01:53

US3022208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:01:53

US3022208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:01:58

US3022208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 17:01:58

US3022208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:03:59

US3022208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '03 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 17:03:59

US3022208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Oct 2020 17:03:59

US3022208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:03:59

US3022208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:04:04

US3022208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 17:04:04

US3022208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 19 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:34:26
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 19 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'no illness visit needed due to no symptoms' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 23:30:27
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 19 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:37:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:04:13

US3022208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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)	16 Oct 2020 16:19:40
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.'	(b) (4), (b) (6)	15 Oct 2020 17:04:34
answered with 'this is correct ' (Site from System).		
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	15 Oct 2020 17:04:13
User entered '14 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 17:04:13

US3022208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Oct 2020 17:04:13

US3022208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:04:13

US3022208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:06:33

US3022208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Oct 2020 17:06:33

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:29

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:29

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:29

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	10 Nov 2020 22:42:29

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 08:43:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 08:43:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:39

US3022208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:39

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

If No, reason not given

Audit	User	Time (GMT)
User opened query 'Per CDM: Please review this field and reconcile with the Dosing Discontinuation form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:49:57
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		13 Nov 2020 23:02:13
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 23:02:13
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	10 Nov 2020 22:42:44
User entered empty.	System	10 Nov 2020 22:42:44
	Shanice Bennett (b) (4)	10 Nov 2020 22:42:44
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 08:43:40

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:11

US3022208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:11

US3022208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:40

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:11

US3022208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:43:11

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 08:43:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shanice Bennett (b) (4)	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:40

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shanice Bennett (b) (4)	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:40

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 22:44:18
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 22:44:11

US3022208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 22:44:18
User entered empty.	System	10 Nov 2020 22:44:11

US3022208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:44:38

US3022208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:44:38

US3022208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:44:38

US3022208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:44:38

US3022208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:44:42

US3022208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 22:44:42

US3022208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:45:33

US3022208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:45:33

US3022208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:45:33

US3022208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:45:33

US3022208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:19

US3022208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 22:47:19

US3022208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:29

US3022208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:29

US3022208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:29

US3022208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 08:43:40

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:29

US3022208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:33

US3022208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 08:43:40

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 22:47:33

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 64'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[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 (055dec66dc3e364a)', Time: '2020-10-21T16:08:18', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ff3fdd77-b0c7-4349-8879-0c8d6a60483f'	System	21 Oct 2020 20:08:39
User entered 'No (N)'	System	21 Oct 2020 20:08:39

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2020-10-21T16:08:29', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ff3fdd77-b0c7-4349-8879-0c8d6a60483f'	System	21 Oct 2020 20:08:39
User entered 'No (N)'	System	21 Oct 2020 20:08:39

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-10-21T16:08:35', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ff3fdd77-b0c7-4349-8879-0c8d6a60483f' User entered '21 Oct 2020 16:08:35'	System	21 Oct 2020 20:08:39
	System	21 Oct 2020 20:08:39

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 71'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[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 (055dec66dc3e364a)', Time: '2020-10-27T20:23:30', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5d404749-42b9-4351-ae1b-85aee5af345d'	System	28 Oct 2020 00:23:40
User entered 'No (N)'	System	28 Oct 2020 00:23:40

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2020-10-27T20:23:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5d404749-42b9-4351-ae1b-85aee5af345d'	System	28 Oct 2020 00:23:40
User entered 'No (N)'	System	28 Oct 2020 00:23:40

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-10-27T20:23:38', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5d404749-42b9-4351-ae1b-85aee5af345d' User entered '27 Oct 2020 20:23:38'	System	28 Oct 2020 00:23:40

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 19:43:38
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Oct 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Oct 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Oct 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Oct 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '31 Oct 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 Nov 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 Nov 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 Nov 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 Nov 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 Nov 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 08:43:40

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 08:43:40

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '14:50'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '19 Oct 2020 14:50'	System	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Height (xxx.x)

Audit	User	Time (GMT)
User entered '174' cm	Shanice Bennett (b) (4)	20 Nov 2020 16:37:22
DataPoint set to visible.	(b) (4) System	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' kg	Shanice Bennett (b) (4)	20 Nov 2020 16:37:22
DataPoint set to visible.	(b) (4) System	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.9' C	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
User entered '18'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '120'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '86'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 08:43:40

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:34

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 08:43:40

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:34

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 08:43:40

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:40

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 08:43:40

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 19 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the Illness Visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:48:52
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 19 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the Illness Visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:35:02
User entered '19 Oct 2020'	Shanice Bennett (b) (4)	20 Nov 2020 16:37:40

US3022208

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 08:43:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:33
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	14 Sep 2020 16:39:35
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:31:56
User entered 'USA-US051-2020-mRNA-1273-P301000003'	System	15 Sep 2020 14:31:39
User entered 'New'	(b) (4), (b) (6)	15 Sep 2020 14:31:39

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:29
User coded data point as SOC: Cardiac disorders, HLT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:47:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	14 Sep 2020 16:47:55
Data point term sent to Coder	System	14 Sep 2020 16:46:45
User entered 'CONGESTIVE HEART FAILURE' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:46:11
Data point term sent to Coder	(b) (4)	14 Sep 2020 16:41:30
User entered 'CONGESTION HEART FAILURE'	System	14 Sep 2020 16:40:40
	Shanice Bennett (b) (4)	
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:31
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:33
User entered 'No (N)'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:35
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:20
User closed query 'PV Query: Please confirm the start date as symptoms started on 08 SEP but start date is listed as 10 SEP. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:01:08
Query 'PV Query: Please confirm the start date as symptoms started on 08 SEP but start date is listed as 10 SEP. ' answered with 'date is correct ' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:32:31
User opened query 'PV Query: Please confirm the start date as symptoms started on 08 SEP but start date is listed as 10 SEP. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 17:16:27
User entered '10 Sep 2020'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:22
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:12
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Sep 2020 16:42:05
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:42:05
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Sep 2020 16:41:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:14
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:41:27
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 16:41:27
User entered '14 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:41:27
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:40:40
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:16
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:08
User closed query 'PV Query: The event intensity is "Grade 4" for this event of Congestive heart failure. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.	(b) (4), (b) (6)	05 Oct 2020 13:01:19
' (Site from Safety). Query 'PV Query: The event intensity is "Grade 4" for this event of Congestive heart failure. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.	Shanice Bennett (b) (4) (b) (4)	02 Oct 2020 21:32:48
' answered with 'yes per PI due to the patient being hospitalized ' (Site from Safety). User opened query 'PV Query: The event intensity is "Grade 4" for this event of Congestive heart failure. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.	(b) (4), (b) (6)	21 Sep 2020 17:52:34
' (Site from Safety). User entered 'Grade 4 (Grade 4)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:07
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Sep 2020 16:42:35
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Sep 2020 16:40:40
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:00
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:02
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:56
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:42:35
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:49
User entered '10 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:42:35
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:51
User entered '14 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:42:35
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:17:53
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:42:35
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:51
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:47
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:46
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:44
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:16:23
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 16:41:27
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 16:40:40
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:16:22
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigation Product Withdrawn. However, Dosing Discontinuation details does not reflect this AE as a reason for discontinuation. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 21:58:56
Query 'Per DM CLR: Action Taken with Investigational Product = Investigation Product Withdrawn. However, Dosing Discontinuation details does not reflect this AE as a reason for discontinuation. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'this is correct' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 23:45:01
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigation Product Withdrawn. However, Dosing Discontinuation details does not reflect this AE as a reason for discontinuation. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:19:21
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:38:48
User closed query 'Per source action taken with IP is IP withdrawn. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:38:46
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'updated' (Site from System).	Shanice Bennett (b) (4)	10 Nov 2020 20:09:37
Query 'Per source action taken with IP is IP withdrawn. Please confirm with source and update accordingly.' answered with 'updated ' (Site from CRA).	Shanice Bennett (b) (4)	10 Nov 2020 20:09:31

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	10 Nov 2020 20:08:54
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:08:54
User opened query 'Per source action taken with IP is IP withdrawn. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	10 Nov 2020 19:04:26
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:41:27
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 08:17:14
	(b) (4), (b) (6)	11 Nov 2020 20:15:16
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:08:54
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'pending medical records' (Site from DM).	Shanice Bennett (b) (4)	02 Oct 2020 21:32:58
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:43:04
User entered '1'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per CDM (CLR Re-Query): response of 'will update' is noted; however the update has not been made. Please reconcil and update Concomitant Medications Form.' answered with 'There are no medications documented in the chart under conmed log for this condition.' (Site from DM).	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 18:48:16
User opened query 'Per CDM (CLR Re-Query): response of 'will update' is noted; however the update has not been made. Please reconcil and update Concomitant Medications Form.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:07:46
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:07:46
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'will update' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 23:45:19
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:20:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:39:02
User closed query 'Per source medication was given. Please reconcile with medical records and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:39:01
Query 'Per source medication was given. Please reconcile with medical records and update accordingly.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:09:42
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:08:54
User opened query 'Per source medication was given. Please reconcile with medical records and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:05:17

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedures are a Diagnostic procedures rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:27:40
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedures are a Diagnostic procedures rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' answered with 'will update' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 23:45:14
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedures are a Diagnostic procedures rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:19:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:16:23
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 20:16:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:15:24
User closed query 'Per source procedures were completed. Please confirm and update. Also please add to concomitant procedures page.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:39:09
Query 'Per source procedures were completed. Please confirm and update. Also please add to concomitant procedures page.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	10 Nov 2020 20:09:48
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:08:54
User opened query 'Per source procedures were completed. Please confirm and update. Also please add to concomitant procedures page.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:15:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per source procedures were completed. Please confirm and update.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:15:03
User opened query 'Per source procedures were completed. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:14:15
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:05:20
Query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae. ' answered with 'sequel is updated' (Site from Safety).	Shanice Bennett (b) (4)	20 Nov 2020 15:53:14
User opened query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae. ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:04:44
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:50:47
User closed query 'Please confirm with source or clarify. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:09:43
Query 'Please confirm with source or clarify. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:27:26
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	13 Nov 2020 23:27:21
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:27:21
User opened query 'Please confirm with source or clarify. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:21:24
User closed query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:15:04
Query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	10 Nov 2020 20:10:34
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 20:10:28
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 20:10:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:10:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:15:53
User opened query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae' . Please specify sequelae.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 17:23:45
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

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Folder: Adverse Events

Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:15:51
User entered 'DUE TO CONGESTIVE HEART FAILURE IS A NEW DIAGNOSIS.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:46:11
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
User entered 'Subject reported that she was hospitalized and being discharged today. On 08Sep2020 she began to have shortness of breath with excretion. On 10Sep2020 she was seen by her PCP and told she had fluid on her lungs and was sent to the ER for an evaluation. She reports she was diagnosed with congestive heart failure and tested positive for COVID-19. She is being prescribed new medications (Losartan and Abilify) but unsure of doses. Pending medical records.' (non-conformant).	System	14 Sep 2020 16:41:27
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	Shanice Bennett (b) (4)	14 Sep 2020 16:41:27
User entered empty.	(b) (4)	
	System	14 Sep 2020 16:40:40
	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per CDM, per DM CLR re-query: Please review and verify if any medications have been taken and update the Con Med page as appropriate. ' answered with 'There were no medications taken or updated on the conmed log' (Site from DM).	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 18:47:45
User closed query 'PV Query: Per the medical record, the patient had worsening SOB for 3 days before coming to ER on 10-SEP-2020. Per the medical record, the patient had dry cough and palpitations for 1 week before coming to ER. Please confirm reconsideration of onset date is necessary. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:05:56
User closed query 'PV Query: Did suicidal ideation prior to the event of congestive heart failure occurred after IP administration? If so, please confirm that suicidal ideation meets definition of AE or SAE. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:05:52
User closed query 'PV Query: Please confirm that cardiomyopathy meets definition of SAE as a diagnosis of congestive heart failure. If so, please reconsider the event term. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:05:47
User closed query 'PV Query: The subject was reported as positive for COVID-19. Please consider adding it to the EDC' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:05:31
User opened query 'Per CDM, per DM CLR re-query: Please review and verify if any medications have been taken and update the Con Med page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:34:04
User closed query 'Per DM CLR: SAE NARRATIVE: SHE IS BEING PRESCRIBED NEW MEDICATIONS (LOSARTAN AND ABILIFY). Please review and confirm if the following medications has been taken by the subject. If yes, please ensure that this information is captured in the appropriate eCRF. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:34:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Per the medical record, the patient had worsening SOB for 3 days before coming to ER on 10-SEP-2020. Per the medical record, the patient had dry cough and palpitations for 1 week before coming to ER. Please confirm reconsideration of onset date is necessary. If not, please explain.' answered with 'subject stated that she denied cough but palpitation yes. ' (Site from Safety).	Shanice Bennett (b) (4)	20 Nov 2020 16:08:54
Query 'PV Query: Did suicidal ideation prior to the event of congestive heart failure occurred after IP administration? If so, please confirm that suicidal ideation meets definition of AE or SAE. If not, please explain.' answered with 'no' (Site from Safety).	Shanice Bennett (b) (4)	20 Nov 2020 16:08:03
Query 'PV Query: Please confirm that cardiomyopathy meets definition of SAE as a diagnosis of congestive heart failure. If so, please reconsider the event term. If not, please explain.' answered with 'confirmed' (Site from Safety).	Shanice Bennett (b) (4)	20 Nov 2020 16:07:46
Query 'PV Query: The subject was reported as positive for COVID-19. Please consider adding it to the EDC' answered with 'I did that and they asked me to remove it due to no symptoms ' (Site from Safety).	Shanice Bennett (b) (4)	20 Nov 2020 16:07:33
User opened query 'PV Query: Per the medical record, the patient had worsening SOB for 3 days before coming to ER on 10-SEP-2020. Per the medical record, the patient had dry cough and palpitations for 1 week before coming to ER. Please confirm reconsideration of onset date is necessary. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:05:45
User opened query 'PV Query: Did suicidal ideation prior to the event of congestive heart failure occurred after IP administration? If so, please confirm that suicidal ideation meets definition of AE or SAE. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:05:24
User opened query 'PV Query: Please confirm that cardiomyopathy meets definition of SAE as a diagnosis of congestive heart failure. If so, please reconsider the event term. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:05:12
User opened query 'PV Query: The subject was reported as positive for COVID-19. Please consider adding it to the EDC' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:04:57

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:18:45
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:15:19
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:15:15
User entered 'UPDATED SAE WITH MEDIAL RECORDS HAVE BEEN EMAILED OVER. MEDICATION AND PROCEDURE. SAE due to Cocaine abuse.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	11 Nov 2020 15:28:31
User closed query 'Please update Narrative with information from medical history. Please also add all medications taken.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:40:21
Query 'Please update Narrative with information from medical history. Please also add all medications taken.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	10 Nov 2020 20:15:04
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	10 Nov 2020 20:14:51
Query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	10 Nov 2020 20:14:45
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:14:39
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 20:14:39

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'updated SAE with medial records have been emailed over. medication and procedure.'	Shanice Bennett (b) (4)	10 Nov 2020 20:14:39
reason for change: Data Entry Error	(b) (4)	
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:08:54
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:08:54
User opened query 'Please update Narrative with information from medical history. Please also add all medications taken.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 18:38:43
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 17:24:00
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 17:23:18
User closed query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:01:28
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:01:26
Query 'Per DM CLR: SAE NARRATIVE: SHE IS BEING PRESCRIBED NEW MEDICATIONS (LOSARTAN AND ABILIFY). Please review and confirm if the following medications has been taken by the subject. If yes, please ensure that this information is captured in the appropriate eCRF. Otherwise, provide clarification.' answered with 'pending medical records' (Site from DM).	Shanice Bennett (b) (4)	02 Oct 2020 21:33:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae' . Please specify sequelae ' answered with 'pending medical records' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:33:13
Query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable. ' answered with 'pending medical records' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:33:06
User opened query 'Per DM CLR: SAE NARRATIVE: SHE IS BEING PRESCRIBED NEW MEDICATIONS (LOSARTAN AND ABILIFY). Please review and confirm if the following medications has been taken by the subject. If yes, please ensure that this information is captured in the appropriate eCRF. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:42:36
User opened query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae' . Please specify sequelae ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 17:17:21
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 17:16:53
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:41:41
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 16:41:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject reported that she was hospitalized and being discharged today. On 08Sep2020 she began to have shortness of breath with excretion. On 10Sep2020 she was seen by her PCP and told she had fluid on her lungs and was sent to the ER for an evaluation. She reports she was diagnosed with congestive heart failure and tested positive for COVID-19. She is being prescribed new medications (Losartan and Abilify) but unsure of doses. Pending medical records.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:41:41
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:40:40
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:40:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:40:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 08:43:40

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 16:42:35

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 08:43:40

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Query 'Please add all conmeds per source. Thank you' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:21:48
User opened query 'Please add all conmeds per source. Thank you' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:42:06
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:47:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:47:43
Data point term sent to Coder	System	27 Aug 2020 21:27:54
User entered 'TYLENOL'	Shanice Bennett (b) (4) (b) (4)	27 Aug 2020 21:26:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 21:27:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 21:27:27
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	27 Aug 2020 21:27:27
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 21:26:54
User entered empty.	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User closed query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of PAIN AT INJECTION SITE does not meet any of the remaining AE reporting criteria, else add an entry and appropriate details to the AE eCRF. Thank you. ' (Site from DM). Query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of PAIN AT INJECTION SITE does not meet any of the remaining AE reporting criteria, else add an entry and appropriate details to the AE eCRF. Thank you. ' answered with 'Because this is pertaining to diary after vaccination ' (Site from DM).	(b) (4), (b) (6) Shanice Bennett (b) (4)	11 Nov 2020 07:21:17 22 Oct 2020 15:42:17
User opened query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of PAIN AT INJECTION SITE does not meet any of the remaining AE reporting criteria, else add an entry and appropriate details to the AE eCRF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:45:02
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT THE INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:45:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT THE INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE did not meet the AE reporting criteria. ' answered with 'no MAAE or SAE ' (Site from DM).	Shanice Bennett (b) (4)	02 Oct 2020 17:36:45
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT THE INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 03:10:46
User entered 'PAIN AT THE INJECTION SITE'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '500'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'mg (mg)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'twice daily (BID)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '21 Aug 2020'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '0'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '21 Aug 2020'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 08:43:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:56:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:56:39
Data point term sent to Coder	System	10 Nov 2020 19:55:47
User entered 'hydrocodone/Acetaminophen'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Chronic Pain'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '7.5/325'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'mg (mg)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'as needed (PRN)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'un UNK 2014'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:06
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 08:43:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:52:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:52:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
Data point term sent to Coder	System	10 Nov 2020 19:56:48
User entered 'polyethylene glycol'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Chronic Constipation'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '17'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'g (g)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'un UNK 2014'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 08:43:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:57:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	10 Nov 2020 19:57:40
Data point term sent to Coder	System	10 Nov 2020 19:56:49
User entered 'Anastrozole'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:18:04
User entered 'No (N)'	(b) (4)	
	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Breast Cancer'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '1'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'mg (mg)'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'un UNK 2014'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 08:43:40

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 08:43:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:38:12
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 20:38:10
	(b) (4)	

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per source date of procedure is 10Sep20. Please confirm with source and update.' answered with 'date is correct. Source has been updated' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 23:31:50
User opened query 'Per source date of procedure is 10Sep20. Please confirm with source and update.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:40:45
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:27
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered '11 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	11 Nov 2020 13:06:42
User entered '10 Sep 2020'	Shanice Bennett (b) (4)	10 Nov 2020 20:38:39

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered 'Electrocardiogram' reason for change:	Shanice Bennett (b) (4)	10 Nov 2020 20:39:16
Data Entry Error	(b) (4)	
User entered 'Congestive Heart Failure'	Shanice Bennett (b) (4)	10 Nov 2020 20:38:39
	(b) (4)	

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4)	10 Nov 2020 20:38:39
	(b) (4)	

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 08:43:40

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 20:38:39
	(b) (4)	

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:43:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per source date of procedure is 10Sep20. Please confirm with source and update' answered with 'date is correct. Source has been updated' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 23:32:02
User opened query 'Per source date of procedure is 10Sep20. Please confirm with source and update' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:41:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered '11 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	11 Nov 2020 13:06:53
User entered '10 Sep 2020'	Shanice Bennett (b) (4)	10 Nov 2020 20:39:39

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:43:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered 'Echocardiogram'	Shanice Bennett (b) (4)	10 Nov 2020 20:39:39
	(b) (4)	

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:43:40

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4)	10 Nov 2020 20:39:39
	(b) (4)	

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 08:43:40

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 20:39:39
	(b) (4)	

US3022208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:40

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:26:03
User entered '10 Sep 2020'	Shanice Bennett (b) (4)	12 Oct 2020 18:10:47
	(b) (4)	

US3022208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:40

Primary reason for dosing discontinuation

Audit	User	Time (GMT)
User closed query 'Per CDM Re-query: it appears IP discontinuation was due to an SAE. Please update to SAE (Specify)' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:53:34
Query 'Per CDM Re-query: it appears IP discontinuation was due to an SAE. Please update to SAE (Specify)' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 18:49:19
User entered 'SAE (specify) (SAE)' reason for change: Per Query Resolution	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 18:49:12
User opened query 'Per CDM Re-query: it appears IP discontinuation was due to an SAE. Please update to SAE (Specify)' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:35:31
Query 'Per CDM Re-Query: please record as 'SAE (Specify) and record Other Specify field with record number only (i.e. AE #1, etc.)' canceled (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:32:08
User opened query 'Per CDM Re-Query: please record as 'SAE (Specify) and record Other Specify field with record number only (i.e. AE #1, etc.)' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:05:48
User closed query 'Per CDM: Kindly clarify the reason for dosing discontinuation since on the AE page SAE #1 of CONGESTIVE HEART FAILURE is recorded as IP withdrawn. Review and reconcile Dosing discontinuation and AE pages as appropriate as per PI discretion. If the reason is SAE, ensure the SAE record number is recorded in the other specify field. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:00:07
Query 'Per CDM: Kindly clarify the reason for dosing discontinuation since on the AE page SAE #1 of CONGESTIVE HEART FAILURE is recorded as IP withdrawn. Review and reconcile Dosing discontinuation and AE pages as appropriate as per PI discretion. If the reason is SAE, ensure the SAE record number is recorded in the other specify field. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:09:29
DataPoint Un-verified.	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:09:22
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:09:22

US3022208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:40

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Kindly clarify the reason for dosing discontinuation since on the AE page SAE #1 of CONGESTIVE HEART FAILURE is recorded as IP withdrawn. Review and reconcile Dosing discontinuation and AE pages as appropriate as per PI discretion. If the reason is SAE, ensure the SAE record number is recorded in the other specify field. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:28:48
User closed query 'Per CDM: Primary reason for dosing discontinuation = Due to SARS-COV-2. Please note that the Covid-19 Assessment folder is not completed and there is no record of COVID-19 diagnosis on the AE page. Please review, reconcile and update as appropriate, else provide clarification in a query response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:48:21
Query 'Per CDM: Primary reason for dosing discontinuation = Due to SARS-COV-2. Please note that the Covid-19 Assessment folder is not completed and there is no record of COVID-19 diagnosis on the AE page. Please review, reconcile and update as appropriate, else provide clarification in a query response. Thank you. ' answered with 'yes because she was diagnosed at the hospital. NO visit needed due to no symptoms' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 21:40:56
User opened query 'Per CDM: Primary reason for dosing discontinuation = Due to SARS-COV-2. Please note that the Covid-19 Assessment folder is not completed and there is no record of COVID-19 diagnosis on the AE page. Please review, reconcile and update as appropriate, else provide clarification in a query response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:02:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:26:03
User entered 'Due to SARS-COV-2 (COVID)'	Shanice Bennett (b) (4)	12 Oct 2020 18:10:47

US3022208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 08:43:40

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: Please record the record line number per CCGs without details (i.e. AE#1 SAE #1, etc.)' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:53:46
Query 'Per CDM: Please record the record line number per CCGs without details (i.e. AE#1 SAE #1, etc.)' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	23 Nov 2020 18:49:23
User entered 'SAE #1' reason for change: Per Query Resolution	(b) (4)	23 Nov 2020 18:49:12
User opened query 'Per CDM: Please record the record line number per CCGs without details (i.e. AE#1 SAE #1, etc.)' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:34:46
Query 'Per CDM: update noted; however please consider recording as AE #1 per CCGs and remove details ' canceled (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:04:03
User opened query 'Per CDM: update noted; however please consider recording as AE #1 per CCGs and remove details ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:03:23
DataPoint Un-verified.	Shanice Bennett (b) (4)	20 Nov 2020 16:09:22
User entered '#1 of CONGESTIVE HEART FAILUR' reason for change: Data Entry Error DataPoint Verified.	Shanice Bennett (b) (4)	20 Nov 2020 16:09:22
	(b) (4), (b) (6)	10 Nov 2020 19:26:03
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Oct 2020 18:10:51
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	12 Oct 2020 18:10:51
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Oct 2020 18:10:47
User entered 'test positive for COVID-19'	Shanice Bennett (b) (4)	12 Oct 2020 18:10:47

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:43:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
User entered '15/Sep/2020 10:34'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 08:43:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:43:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
User entered '05/Oct/2020 09:01'	System	05 Oct 2020 13:01:46

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 08:43:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:46:58
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 13:01:46

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:43:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
User entered '08/Oct/2020 16:47'	System	08 Oct 2020 16:47:15

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 08:43:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:15:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
User entered 'I'	(b) (4), (b) (6)	08 Oct 2020 16:47:15

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:43:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '11/Nov/2020 20:16'	System	11 Nov 2020 20:16:11

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 08:43:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:45:41
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 20:16:11

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:43:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '16/Nov/2020 08:45'	System	16 Nov 2020 13:45:50

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 08:43:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 00:13:20
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 13:45:50

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 26 Nov 2020 08:43:40

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 08:43:40

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Nov/2020 19:13'	System	24 Nov 2020 00:13:37

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 08:43:40

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 00:13:37