

US3742463 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:22:22

All time stamps listed in this document are displayed in GMT

US3742463

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:26:01

Generated On: 12 Aug 2021 13:22:22

[Participant ID](#)

US3742463

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

US3742463

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Date of Birth (MMM yyyy)	(b) (6) 1997
Age	23
Age Units	YEARS
Age (Derived)	23
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	True
Black	False
Asian	True
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

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Date of Informed Consent (<i>dd MMM yyyy</i>)	23 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:57:27

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Condition	HYPERHIDROSIS
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Condition	CAT DANDER ALLERGY
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 SEP 2020
Time of assessment (00:00-23:59)	08:49 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 08:49
Height (xxx.x)	65.0 in
Weight (xxx.x)	137.0 lb
BMI (xxx.x)	22.84566 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	099.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	057 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	075 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:57:27

Generated On: 12 Aug 2021 13:22:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 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

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Date of assessment (dd MMM yyyy) 23 SEP 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:57:27

Generated On: 12 Aug 2021 13:22:22

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	26 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:57:29

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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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:57:29

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

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

What was the participant's randomization number? 115603

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

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Height	65.0 in
Weight	136.0 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Height	65.0 in
Weight	136.0 lb
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)	26 SEP 2020
Time of assessment (00:00-23:59)	08:26 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 08:26
Temperature (xxx.x)	098.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	060 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	067 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Height	65.0 in
Weight	136.0 lb
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)	26 SEP 2020
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 10:44
Temperature (xxx.x)	098.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	053 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	077 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 SEP 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: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 26 SEP 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 SEP 2020

What was the treatment time? (00:00-23:59) 09:58 (24 HR)

Treatment Date and Time (derived) 26 SEP 2020 09:58

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 SEP 2020

Collection time (00:00-23:59)

09:08 (24 HR)

Collection date and time (derived)

26 SEP 2020 09:08

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Collection date (dd MMM yyyy)			26 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:09	26 SEP 2020 09:09
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

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: 12 Aug 2021 13:22:22

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 10:46

PC Open Date & Time

26 SEP 2020 10:18

PC Close Date & Time

26 SEP 2020 12:48

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	26 SEP 2020 20:22
PC Open Date & Time	26 SEP 2020 13:43
PC Close Date & Time	27 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:49

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 19:36

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 23:00

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 21:43

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 20:47

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 22:07

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 10:43

PC Open Date & Time

26 SEP 2020 10:18

PC Close Date & Time

26 SEP 2020 12:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

26 SEP 2020 20:18

PC Open Date & Time

26 SEP 2020 13:43

PC Close Date & Time

27 SEP 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 19:35

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 19:34

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

29 SEP 2020 22:59

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 19:33

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 20:47

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 21:54

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 10:45
PC Open Date & Time	26 SEP 2020 10:18
PC Close Date & Time	26 SEP 2020 12:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 20:19
PC Open Date & Time	26 SEP 2020 13:43
PC Close Date & Time	27 SEP 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

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 ☒

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:34
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

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 ☒

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EAB) (1725)

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

		Yes <input type="checkbox"/>
PC Time stamp	28 SEP 2020 19:34	
PC Open Date & Time	28 SEP 2020 12:00	
PC Close Date & Time	29 SEP 2020 11:59	

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 22:59
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

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 ☒

PRODUCTION RELEASE (v12.003

53 of 1831

EAB) (1725)

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 19:32
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 20:47
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 21:54
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3742463

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742463

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742463

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742463

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	07:26 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 07:26
Temperature (xxx.x)	097.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	055 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	08:54 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 08:54
Temperature (xxx.x)	098.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	055 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG

US3742463

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3742463

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	27 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	27 OCT 2020
Collection time	07:50
Collection date and time (derived)	27 OCT 2020 07:50

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 27 OCT 2020

What was the treatment time? (00:00-23:59) 08:12 (24 HR)

Treatment Date and Time (derived) 27 OCT 2020 08:12

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

What was the frequency of the study treatment dosing? ONCE

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

US3742463

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 OCT 2020

Collection time (00:00-23:59)

07:37 (24 HR)

Collection date and time (derived)

27 OCT 2020 07:37

US3742463

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Collection date (dd MMM yyyy)			27 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:50	27 OCT 2020 07:50
Nasopharyngeal Swab 2	No		

US3742463

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:57:29

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 08:50

PC Open Date & Time

27 OCT 2020 08:32

PC Close Date & Time

27 OCT 2020 11:02

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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 100.0 °F

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

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

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

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

PC Time Stamp 27 OCT 2020 20:43

PC Open Date & Time 27 OCT 2020 11:57

PC Close Date & Time 28 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

28 OCT 2020 20:13

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 22:17

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 31 OCT 2020 11:38

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 OCT 2020 21:14

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 NOV 2020 21:46

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 NOV 2020 22:21

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 08:46

PC Open Date & Time

27 OCT 2020 08:32

PC Close Date & Time

27 OCT 2020 11:02

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

27 OCT 2020 20:41

PC Open Date & Time

27 OCT 2020 11:57

PC Close Date & Time

28 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 OCT 2020 20:12

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 OCT 2020 22:16

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 OCT 2020 06:13

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 OCT 2020 21:14

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 NOV 2020 21:45

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 NOV 2020 22:22

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

No ☒

Yes ☐

PC Time stamp	27 OCT 2020 08:45
PC Open Date & Time	27 OCT 2020 08:32
PC Close Date & Time	27 OCT 2020 11:02

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

No ☒

Yes ☐

PC Time stamp	27 OCT 2020 20:40
PC Open Date & Time	27 OCT 2020 11:57
PC Close Date & Time	28 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

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 ☒

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EAB) (1725)

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 20:13
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

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 ☒

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EAB) (1725)

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 22:16
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 06:14
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

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 ☒

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EAB) (1725)

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 21:13
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 21:45
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

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 ☒

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 22:22
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3742463

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742463

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742463

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742463

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:57:26

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:57:30

Generated On: 12 Aug 2021 13:22:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:57:30

Generated On: 12 Aug 2021 13:22:22

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3742463

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:57:30

Generated On: 12 Aug 2021 13:22:22

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.

US3742463

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:57:30

Generated On: 12 Aug 2021 13:22:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 NOV 2020

Collection time (00:00-23:59)

08:25 (24 HR)

Collection date and time (derived)

21 NOV 2020 08:25

US3742463

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:57:30

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 09:47:33
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 12:19:28
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 11:19:22
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you 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 checked="" 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 checked="" type="radio"/>
Date and time of submission	14 DEC 2020 11:20:58
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	21 DEC 2020 13:16:04
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 DEC 2020 13:05:18
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 06:42:33

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 11:32:59
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 06:42:54
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 JAN 2021 07:43:12
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 FEB 2021 10:26:46
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

Date and time of submission

08 FEB 2021 14:02:59

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 10:34:15

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 07:10:54
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 11:05:26
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 09:28:28

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

Date and time of submission

15 MAR 2021 06:15:44

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 09:57:27

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 07:42:31

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 APR 2021 07:23:34
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 APR 2021 06:19:28
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you 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 checked="" 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 checked="" type="radio"/>
Date and time of submission	19 APR 2021 05:55:33
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 21:57:09

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

Date and time of submission

03 MAY 2021 06:26:31

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

21 MAY 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

28 MAY 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

06 AUG 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	20 AUG 2021 23:59
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US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

27 AUG 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

17 SEP 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 SEP 2021 00:01
Patient Cloud Close Date & Time	24 SEP 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 369
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 <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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

15 OCT 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

22 OCT 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2021 00:01
Patient Cloud Close Date & Time	29 OCT 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

19 NOV 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

29 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

06 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

24 DEC 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

03 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JAN 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 <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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 FEB 2022 00:01
Patient Cloud Close Date & Time	25 FEB 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

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07 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

14 MAR 2022 00:01

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18 MAR 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

21 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAR 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

28 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 APR 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 <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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

18 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 <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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 <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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

27 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2022 00:01
Patient Cloud Close Date & Time	15 JUL 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 <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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

22 JUL 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

25 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 ☐

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

05 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

30 SEP 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

21 OCT 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

28 OCT 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

04 NOV 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

11 NOV 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2022 00:01
Patient Cloud Close Date & Time	18 NOV 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Open Date & Time](#)

21 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2022 23:59

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

[Patient Cloud Close Date & Time](#)

02 DEC 2022 23:59

US3742463

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:22:22

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 11:05:18

US3742463

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742463

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742463

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3742463

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 MAR 2021

Please select one status for the follow-up contact Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

PER PARTICIPANT PAP SMEAR
WILL NOT BE EVALUATED FOR
1 YEAR. NO TREATMENT
REQUIRED NO ADDITIONAL
EVALUATION REQUIRED.

US3742463

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 19 Apr 2021 14:21:24

Generated On: 12 Aug 2021 13:22:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Apr 2021 14:21:24

Generated On: 12 Aug 2021 13:22:22

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3742463

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Apr 2021 14:21:24

Generated On: 12 Aug 2021 13:22:22

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.

US3742463

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Apr 2021 14:21:24

Generated On: 12 Aug 2021 13:22:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 APR 2021

Collection time (00:00-23:59)

08:30 (24 HR)

Collection date and time (derived)

17 APR 2021 08:30

US3742463

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 14:21:24

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742463

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

US3742463

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742463

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:22:22

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"/>

US3742463

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:22:22

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

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

Visit date (dd MMM yyyy)	25 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:52:46

Generated On: 12 Aug 2021 13:22:22

Date of updated informed consent (dd MMM yyyy) 25 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 25 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00-23:59)

07:39 (24 HR)

Collection date and time (derived)

25 JAN 2021 07:39

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

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

Collection date (dd MMM yyyy)	25 JAN 2021
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Collection time (00:00 - 23:59)	07:42
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Collection Date and Time (derived)	25 JAN 2021 07:42
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US3742463

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

AEID

Adverse event

URINARY TRACT INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

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 type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

AEID

Adverse event

TRICHOMONIASIS VAGINALIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

07 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

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 type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

AEID	
Adverse event	ABNORMAL PAP RESULT
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

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 type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:26:02

Generated On: 12 Aug 2021 13:22:22

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication HYPERHIDROSIS

Dose per administration 100

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 21:53:57

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Name of Medication NEXPLANON

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify INPLANT

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

If frequency is Other, specify CONTINUOUS FOR 3 YEARS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	SUBDERMAL	
Start date (dd MMM yyyy)	10 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN AND
FEVER

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED PAIN AND
FEVER

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

	Intraocular	<input type="checkbox"/>
	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)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		07 DEC 2020
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication URINARY TRACT INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

	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)	30 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication TRICHOMONIASIS VAGINALIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

	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)	11 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 21:53:57

Generated On: 12 Aug 2021 13:22:22

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:22:22

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:22:22

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3742463 (Prod: University of Maryland School of Medicine)

US3742463

Form: Participant Creation

Generated On: 12 Aug 2021 13:22:22

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'US3742463'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 11:59:18

US3742463

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Sep 2020 20:16:44

US3742463

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '23 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 11:59:20

US3742463

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	23 Sep 2020 20:16:44

US3742463

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'SCRN'	System	23 Sep 2020 20:16:44

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered (b) (6) 1997'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 11:59:21

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '23'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'YEARS'	System	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered '23'	System	26 Sep 2020 14:09:45

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Female (F)'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'I'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'I'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:22:22

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	Sherry McCammon (b) (4)	23 Sep 2020 20:18:04

US3742463

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:22

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:09:45

US3742463

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'Sep 2020'	System	26 Sep 2020 14:09:45

US3742463

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered '2020'	System	26 Sep 2020 14:09:45

US3742463

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:22

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:09:45

US3742463

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:09:45

US3742463

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:22

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:09:45

US3742463

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:22

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:09:45

US3742463

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:22

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:09:45

US3742463

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:22

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 11:59:20

US3742463

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:22:22

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'I'	System	26 Sep 2020 14:09:59

US3742463

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:09:59

US3742463

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:22:22

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:03

US3742463

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Apocrine and eccrine gland disorders, PT: Hyperhidrosis, LLT: Hyperhidrosis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 14:04:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 14:04:45
Data point term sent to Coder	System	28 Sep 2020 14:03:39
User entered 'HYPERHIDROSIS' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:03:02
Data point term sent to Coder	System	28 Sep 2020 14:01:32
User entered 'HYPERHIDEOSIS'	(b) (4), (b) (6)	28 Sep 2020 14:01:27

US3742463

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'UN UNK 2009'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:27

US3742463

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:27

US3742463

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:27

US3742463

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:27

US3742463

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:27

US3742463

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'Jan 2009'	System	28 Sep 2020 14:01:27

US3742463

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:22

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered '2009'	System	28 Sep 2020 14:01:27

US3742463

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered empty.	System	28 Sep 2020 14:01:27

US3742463

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered empty.	System	28 Sep 2020 14:01:27

US3742463

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergic to cats - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 14:03:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 14:03:42
Data point term sent to Coder	System	28 Sep 2020 14:02:37
User entered 'CAT DANDER ALLERGY'	(b) (4), (b) (6)	28 Sep 2020 14:01:47

US3742463

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:47

US3742463

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:47

US3742463

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:47

US3742463

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:47

US3742463

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:01:47

US3742463

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'Jan 2013'	System	28 Sep 2020 14:01:47

US3742463

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered '2013'	System	28 Sep 2020 14:01:47

US3742463

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered empty.	System	28 Sep 2020 14:01:47

US3742463

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered empty.	System	28 Sep 2020 14:01:47

US3742463

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fish allergy - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 14:03:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 14:03:41
Data point term sent to Coder	System	28 Sep 2020 14:02:37
User entered 'FISH ALLERGY'	(b) (4), (b) (6)	28 Sep 2020 14:02:04

US3742463

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:02:04

US3742463

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:02:04

US3742463

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:22

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:02:04

US3742463

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:02:04

US3742463

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:22

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:02:04

US3742463

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:22

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'Jan 2015'	System	28 Sep 2020 14:02:04

US3742463

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered '2015'	System	28 Sep 2020 14:02:04

US3742463

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered empty.	System	28 Sep 2020 14:02:04

US3742463

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered empty.	System	28 Sep 2020 14:02:04

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)' reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:23:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '23 Sep 2020' reason for change: New Information	(b) (4)	
	Hassan Haji (b) (4)	04 Nov 2020 14:23:42
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Sep 2020 13:50:30
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	28 Sep 2020 13:50:30
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:30
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	28 Sep 2020 13:49:44
User entered '26 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '08:49' reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:23:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:30
User entered '08:30'	(b) (4), (b) (6)	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered '23 Sep 2020 08:49'	System	04 Nov 2020 14:23:42
User entered empty.	System	28 Sep 2020 13:50:30
User entered '26 Sep 2020 08:30'	System	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '65.0' in reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:23:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:30
User entered '65.0' in	(b) (4), (b) (6)	28 Sep 2020 13:49:44
DataPoint set to visible.	System	26 Sep 2020 14:09:59

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '137.0' lb reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:23:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:30
User entered '136.0' lb	(b) (4), (b) (6)	28 Sep 2020 13:49:44
DataPoint set to visible.	System	26 Sep 2020 14:09:59

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered '22.84566'	System	04 Nov 2020 14:23:42
User entered empty.	System	28 Sep 2020 13:50:30
User entered '22.67890'	System	28 Sep 2020 13:49:44
DataPoint set to visible.	System	26 Sep 2020 14:09:59

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'kg/m2'	System	04 Nov 2020 14:23:42
User entered empty.	System	28 Sep 2020 13:50:30
User entered 'kg/m2'	System	28 Sep 2020 13:49:44
DataPoint set to visible.	System	26 Sep 2020 14:09:59

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	04 Nov 2020 14:23:58
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	04 Nov 2020 14:23:58
User entered '099.0' F reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:23:58
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	04 Nov 2020 14:23:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Nov 2020 14:24:07
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	04 Nov 2020 14:24:07
User entered 'Oral (Oral)' reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:24:07
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	04 Nov 2020 14:23:58
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '057' reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:23:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'bpm'	System	04 Nov 2020 14:23:42
User entered empty.	System	28 Sep 2020 13:50:30
User entered 'bpm'	System	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '18' reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:23:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'breaths/min'	System	04 Nov 2020 14:23:42
User entered empty.	System	28 Sep 2020 13:50:30
User entered 'breaths/min'	System	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '115' reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:23:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'mmHg'	System	04 Nov 2020 14:23:42
User entered empty.	System	28 Sep 2020 13:50:30
User entered 'mmHg'	System	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '075' reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:23:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:30
User entered missing code ND - Not Done.	(b) (4), (b) (6)	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'mmHg'	System	04 Nov 2020 14:23:42
User entered empty.	System	28 Sep 2020 13:50:30
User entered 'mmHg'	System	28 Sep 2020 13:49:44

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53

US3742463

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53

US3742463

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)' reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:24:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 13:48:45

US3742463

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '23 Sep 2020' reason for change: New Information	Hassan Haji (b) (4)	04 Nov 2020 14:24:55
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:50:50
User entered '26 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 13:48:45

US3742463

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:22

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User closed query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	(b) (4)	28 Sep 2020 13:54:01
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 13:54:01
User opened query 'Date of Assessment is after Date of Informed Consent. Please correct.' (Site from System).	System	28 Sep 2020 13:52:11
User entered '26 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 13:52:11

US3742463

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:52:11

US3742463

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:52:11

US3742463

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:22

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:52:11

US3742463

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:52:11

US3742463

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:22

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:52:11

US3742463

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:52:11

US3742463

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:22:22

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:52:11

US3742463

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User closed query 'Per CDM: Please clarify why Was the pregnancy test performed? is NO for Screening Visit. Kindly note as per the protocol p. 105, Pregnancy Test is scheduled to be performed at Screening. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 12:21:38
Query 'Per CDM: Please clarify why Was the pregnancy test performed? is NO for Screening Visit. Kindly note as per the protocol p. 105, Pregnancy Test is scheduled to be performed at Screening. Please review and reconcile. ' answered with 'ENTRY ADJUSTED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Oct 2020 14:22:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Oct 2020 14:22:37
User opened query 'Per CDM: Please clarify why Was the pregnancy test performed? is NO for Screening Visit. Kindly note as per the protocol p. 105, Pregnancy Test is scheduled to be performed at Screening. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 08:08:03
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 13:54:22

US3742463

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '26 Sep 2020' reason for change: Data Entry Error	(b) (4)	02 Oct 2020 14:22:37
User entered empty.	Kaitlin Mason (b) (4)	28 Sep 2020 13:54:22
	(b) (4)	
	(b) (4), (b) (6)	

US3742463

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Urine (URINE)' reason for change:	(b) (4)	
Data Entry Error	Kaitlin Mason (b) (4)	02 Oct 2020 14:22:37
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 13:54:22

US3742463

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	02 Oct 2020 14:22:37
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 13:54:22

US3742463

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User closed query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:50:38
Query 'per CDM: please input yes or no in this field' answered with 'NOT COLLECTED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	12 Oct 2020 13:47:57
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	12 Oct 2020 13:47:53
User opened query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 14:38:13
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 13:54:22

US3742463

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:54:22

US3742463

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:54:22

US3742463

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered empty.	System	28 Sep 2020 13:54:22

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:22:22

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:31:37

US3742463

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User closed query 'per CDM: please confirm whether or not visit was performed' (Site from DM).	(b) (4)	
Query 'per CDM: please confirm whether or not visit was performed' answered with 'VISIT WAS PERFORMED AND DATA HAS BEEN ENTERED' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 15:09:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:06:04
User opened query 'per CDM: please confirm whether or not visit was performed' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:05:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 19:39:19
User entered 'Yes (Y)'	Kaitlin Mason (b) (4)	02 Oct 2020 14:23:00
	(b) (4)	
	(b) (4), (b) (6)	26 Sep 2020 14:07:24

US3742463

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '26 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:05:39
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	02 Oct 2020 14:23:00
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:07:24

US3742463

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:05:39
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	02 Oct 2020 14:23:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Sep 2020 14:07:24

US3742463

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'VISIT1'	System	26 Sep 2020 14:07:24

US3742463

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '26 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 13:42:20

US3742463

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '115603'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 13:42:20

US3742463

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Sep 2020 13:42:20

US3742463

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:08:03

US3742463

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:08:03

US3742463

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:08:03

US3742463

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:22

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:08:03

US3742463

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:22

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:08:03

US3742463

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:32:15
DataPoint set to visible.	System	26 Sep 2020 14:09:45

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '65.0' in	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:22

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '136.0' lb	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '65.0' in	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:22

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '136.0' lb	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '08:26'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '26 Sep 2020 08:26'	System	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '098.8' F	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '060'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'bpm'	System	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '14'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'breaths/min'	System	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '116'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'mmHg'	System	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '067'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'mmHg'	System	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:22

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '65.0' in	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:22:22

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '136.0' lb	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '10:44'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '26 Sep 2020 10:44'	System	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '098.0' F	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '053'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'bpm'	System	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '16'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'breaths/min'	System	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '123'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'mmHg'	System	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '077'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'mmHg'	System	28 Sep 2020 14:00:21

US3742463

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:55:02

US3742463

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:55:02

US3742463

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:56:28

US3742463

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:56:28

US3742463

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:56:28

US3742463

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:56:28

US3742463

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:56:28

US3742463

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:56:28

US3742463

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:56:28

US3742463

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered empty.	System	28 Sep 2020 13:56:28

US3742463

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:11:48

US3742463

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:11:48

US3742463

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:11:48

US3742463

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 14:11:48

US3742463

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:11:48

US3742463

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '09:58'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:11:48

US3742463

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '26 Sep 2020 09:58'	System	26 Sep 2020 14:11:48

US3742463

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Sep 2020 14:11:48

US3742463

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'ONCE'	System	26 Sep 2020 14:11:48

US3742463

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 14:11:48

US3742463

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:56:48

US3742463

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:56:48

US3742463

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '09:08'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:56:48

US3742463

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '26 Sep 2020 09:08'	System	28 Sep 2020 13:56:48

US3742463

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:22:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '26 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:57:03

US3742463

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 13:57:03

US3742463

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:57:03

US3742463

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '09:09'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:57:03

US3742463

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '26 Sep 2020 09:09'	System	28 Sep 2020 13:57:03

US3742463

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 13:57:03

US3742463

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:57:03

US3742463

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 13:57:03

US3742463

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered empty.	System	28 Sep 2020 13:57:03

US3742463

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:00:45

US3742463

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '1'	System	28 Sep 2020 14:00:45

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:46:45', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6858c36b-56e5-4ee6-a991-4aff366d9176'	System	26 Sep 2020 14:47:01
User entered 'Yes (Y)'	System	26 Sep 2020 14:47:01

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:46:51', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6858c36b-56e5-4ee6-a991-4aff366d9176'	System	26 Sep 2020 14:47:01
User entered '98.0'	System	26 Sep 2020 14:47:01

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:46:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6858c36b-56e5-4ee6-a991-4aff366d9176'	System	26 Sep 2020 14:47:01
User entered 'No (N)'	System	26 Sep 2020 14:47:01

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:46:57', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6858c36b-56e5-4ee6-a991-4aff366d9176'	System	26 Sep 2020 14:47:01
User entered '26 Sep 2020 10:46'	System	26 Sep 2020 14:47:01

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '26 Sep 2020 10:18'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '26 Sep 2020 12:48'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:19:22', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a8f3ae62-198f-4980-ae36-24ca3515f598'	System	27 Sep 2020 00:22:49
User entered 'Yes (Y)'	System	27 Sep 2020 00:22:49

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:22:40', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a8f3ae62-198f-4980-ae36-24ca3515f598'	System	27 Sep 2020 00:22:49
User entered '98.0'	System	27 Sep 2020 00:22:49

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:22:43', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a8f3ae62-198f-4980-ae36-24ca3515f598'	System	27 Sep 2020 00:22:49
User entered 'No (N)'	System	27 Sep 2020 00:22:49

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:22:46', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a8f3ae62-198f-4980-ae36-24ca3515f598'	System	27 Sep 2020 00:22:49
User entered '26 Sep 2020 20:22'	System	27 Sep 2020 00:22:49

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '26 Sep 2020 13:43'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 2'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T20:49:18', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '7fbec072-fe73-4089-b095-efb21b7189b4'	System	28 Sep 2020 00:49:35
User entered 'Yes (Y)'	System	28 Sep 2020 00:49:35

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T20:49:22', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '7fbec072-fe73-4089-b095-efb21b7189b4'	System	28 Sep 2020 00:49:35
User entered '98.2'	System	28 Sep 2020 00:49:35

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T20:49:27', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '7fbec072-fe73-4089-b095-efb21b7189b4'	System	28 Sep 2020 00:49:35
User entered 'No (N)'	System	28 Sep 2020 00:49:35

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T20:49:31', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '7fbec072-fe73-4089-b095-efb21b7189b4'	System	28 Sep 2020 00:49:35
User entered '27 Sep 2020 20:49'	System	28 Sep 2020 00:49:35

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 3'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:57', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '61a02649-8f06-441b-9895-2a7ef0e58a06'	System	28 Sep 2020 23:36:32
User entered 'Yes (Y)'	System	28 Sep 2020 23:36:32

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:36:21', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '61a02649-8f06-441b-9895-2a7ef0e58a06'	System	28 Sep 2020 23:36:32
User entered '97.7'	System	28 Sep 2020 23:36:32

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:36:24', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '61a02649-8f06-441b-9895-2a7ef0e58a06'	System	28 Sep 2020 23:36:32
User entered 'No (N)'	System	28 Sep 2020 23:36:32

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:36:27', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '61a02649-8f06-441b-9895-2a7ef0e58a06'	System	28 Sep 2020 23:36:32
User entered '28 Sep 2020 19:36'	System	28 Sep 2020 23:36:32

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 4'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:59:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6ce4579f-4279-490b-b2a3-b093b527d063'	System	30 Sep 2020 03:00:20
User entered 'Yes (Y)'	System	30 Sep 2020 03:00:20

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T23:00:11', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6ce4579f-4279-490b-b2a3-b093b527d063'	System	30 Sep 2020 03:00:20
User entered '97.8'	System	30 Sep 2020 03:00:20

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T23:00:14', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6ce4579f-4279-490b-b2a3-b093b527d063'	System	30 Sep 2020 03:00:20
User entered 'No (N)'	System	30 Sep 2020 03:00:20

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T23:00:18', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6ce4579f-4279-490b-b2a3-b093b527d063'	System	30 Sep 2020 03:00:20
User entered '29 Sep 2020 23:00'	System	30 Sep 2020 03:00:20

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 5'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T21:42:47', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '05972116-a809-489c-9d17-44bb30a249f5'	System	01 Oct 2020 01:43:59
User entered 'Yes (Y)'	System	01 Oct 2020 01:43:59

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T21:43:50', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '05972116-a809-489c-9d17-44bb30a249f5'	System	01 Oct 2020 01:43:59
User entered '97.8'	System	01 Oct 2020 01:43:59

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T21:43:52', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '05972116-a809-489c-9d17-44bb30a249f5'	System	01 Oct 2020 01:43:59
User entered 'No (N)'	System	01 Oct 2020 01:43:59

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T21:43:55', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '05972116-a809-489c-9d17-44bb30a249f5'	System	01 Oct 2020 01:43:59
User entered '30 Sep 2020 21:43'	System	01 Oct 2020 01:43:59

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 6'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:18', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f1fde172-84d6-4ebf-9112-42b9811ac5b2'	System	02 Oct 2020 00:47:29
User entered 'Yes (Y)'	System	02 Oct 2020 00:47:29

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:21', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f1fde172-84d6-4ebf-9112-42b9811ac5b2'	System	02 Oct 2020 00:47:29
User entered '98.7'	System	02 Oct 2020 00:47:29

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:23', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f1fde172-84d6-4ebf-9112-42b9811ac5b2'	System	02 Oct 2020 00:47:29
User entered 'No (N)'	System	02 Oct 2020 00:47:29

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:25', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f1fde172-84d6-4ebf-9112-42b9811ac5b2'	System	02 Oct 2020 00:47:29
User entered '01 Oct 2020 20:47'	System	02 Oct 2020 00:47:29

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 7'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:54:29', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '132a3b0b-af2c-4153-ac5d-bf87e67e0337'	System	03 Oct 2020 02:08:00
User entered 'Yes (Y)'	System	03 Oct 2020 02:08:00

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T22:07:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '132a3b0b-af2c-4153-ac5d-bf87e67e0337'	System	03 Oct 2020 02:08:00
User entered '97.5'	System	03 Oct 2020 02:08:00

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T22:07:50', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '132a3b0b-af2c-4153-ac5d-bf87e67e0337'	System	03 Oct 2020 02:08:00
User entered 'No (N)'	System	03 Oct 2020 02:08:00

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T22:07:56', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '132a3b0b-af2c-4153-ac5d-bf87e67e0337'	System	03 Oct 2020 02:08:00
User entered '02 Oct 2020 22:07'	System	03 Oct 2020 02:08:00

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:43:17', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1e52b9a4-45a9-4d8c-85b7-e997e26904b6'	System	26 Sep 2020 14:43:49
User entered 'None (1)'	System	26 Sep 2020 14:43:49

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:43:20', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1e52b9a4-45a9-4d8c-85b7-e997e26904b6'	System	26 Sep 2020 14:43:49
User entered 'No (N)'	System	26 Sep 2020 14:43:49

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:43:23', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1e52b9a4-45a9-4d8c-85b7-e997e26904b6'	System	26 Sep 2020 14:43:49
User entered 'No (N)'	System	26 Sep 2020 14:43:49

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:43:35', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1e52b9a4-45a9-4d8c-85b7-e997e26904b6'	System	26 Sep 2020 14:43:49
User entered 'None (1)'	System	26 Sep 2020 14:43:49

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:43:45', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1e52b9a4-45a9-4d8c-85b7-e997e26904b6'	System	26 Sep 2020 14:43:49
User entered '26 Sep 2020 10:43'	System	26 Sep 2020 14:43:49

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '26 Sep 2020 10:18'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '26 Sep 2020 12:48'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:18:29', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '90263787-e470-43bd-974b-b117fdf773dc'	System	27 Sep 2020 00:18:44
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 00:18:44

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:18:31', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '90263787-e470-43bd-974b-b117fdf773dc'	System	27 Sep 2020 00:18:44
User entered 'No (N)'	System	27 Sep 2020 00:18:44

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:18:34', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '90263787-e470-43bd-974b-b117fdf773dc'	System	27 Sep 2020 00:18:44
User entered 'No (N)'	System	27 Sep 2020 00:18:44

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:18:37', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '90263787-e470-43bd-974b-b117fdf773dc'	System	27 Sep 2020 00:18:44
User entered 'None (1)'	System	27 Sep 2020 00:18:44

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:18:42', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '90263787-e470-43bd-974b-b117fdf773dc'	System	27 Sep 2020 00:18:44
User entered '26 Sep 2020 20:18'	System	27 Sep 2020 00:18:44

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '26 Sep 2020 13:43'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 2'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:35:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'abdddc9a-f087-48af-8f3c-361c38da4e37'	System	27 Sep 2020 23:35:47
User entered 'None (1)'	System	27 Sep 2020 23:35:47

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:35:07', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'abdddc9a-f087-48af-8f3c-361c38da4e37'	System	27 Sep 2020 23:35:47
User entered 'No (N)'	System	27 Sep 2020 23:35:47

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:35:09', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'abdddc9a-f087-48af-8f3c-361c38da4e37'	System	27 Sep 2020 23:35:47
User entered 'No (N)'	System	27 Sep 2020 23:35:47

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:35:14', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'abdddc9a-f087-48af-8f3c-361c38da4e37'	System	27 Sep 2020 23:35:47
User entered 'None (1)'	System	27 Sep 2020 23:35:47

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:35:42', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'abdddc9a-f087-48af-8f3c-361c38da4e37'	System	27 Sep 2020 23:35:47
User entered '27 Sep 2020 19:35'	System	27 Sep 2020 23:35:47

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 3'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:42', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '81fdd37f-76fb-44fd-a47f-84f412b2a440'	System	28 Sep 2020 23:34:55
User entered 'None (1)'	System	28 Sep 2020 23:34:55

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:44', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '81fdd37f-76fb-44fd-a47f-84f412b2a440'	System	28 Sep 2020 23:34:55
User entered 'No (N)'	System	28 Sep 2020 23:34:55

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:46', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '81fdd37f-76fb-44fd-a47f-84f412b2a440'	System	28 Sep 2020 23:34:55
User entered 'No (N)'	System	28 Sep 2020 23:34:55

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:47', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '81fdd37f-76fb-44fd-a47f-84f412b2a440'	System	28 Sep 2020 23:34:55
User entered 'None (1)'	System	28 Sep 2020 23:34:55

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '81fdd37f-76fb-44fd-a47f-84f412b2a440'	System	28 Sep 2020 23:34:55
User entered '28 Sep 2020 19:34'	System	28 Sep 2020 23:34:55

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 4'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:59:07', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a2cb0b59-07fb-4d28-b404-feecbb61b36f'	System	30 Sep 2020 02:59:48
User entered 'None (1)'	System	30 Sep 2020 02:59:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:59:10', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a2cb0b59-07fb-4d28-b404-feecbb61b36f'	System	30 Sep 2020 02:59:48
User entered 'No (N)'	System	30 Sep 2020 02:59:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:59:36', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a2cb0b59-07fb-4d28-b404-feecbb61b36f'	System	30 Sep 2020 02:59:48
User entered 'No (N)'	System	30 Sep 2020 02:59:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:59:39', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a2cb0b59-07fb-4d28-b404-feecbb61b36f'	System	30 Sep 2020 02:59:48
User entered 'None (1)'	System	30 Sep 2020 02:59:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:59:45', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a2cb0b59-07fb-4d28-b404-feeecbb61b36f'	System	30 Sep 2020 02:59:48
User entered '29 Sep 2020 22:59'	System	30 Sep 2020 02:59:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 5'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:32:58', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6954c232-948f-41dd-908d-2833ff685330'	System	30 Sep 2020 23:33:16
User entered 'None (1)'	System	30 Sep 2020 23:33:16

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:33:02', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6954c232-948f-41dd-908d-2833ff685330'	System	30 Sep 2020 23:33:16
User entered 'No (N)'	System	30 Sep 2020 23:33:16

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:33:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6954c232-948f-41dd-908d-2833ff685330'	System	30 Sep 2020 23:33:16
User entered 'No (N)'	System	30 Sep 2020 23:33:16

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:33:07', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6954c232-948f-41dd-908d-2833ff685330'	System	30 Sep 2020 23:33:16
User entered 'None (1)'	System	30 Sep 2020 23:33:16

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:33:12', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6954c232-948f-41dd-908d-2833ff685330'	System	30 Sep 2020 23:33:16
User entered '30 Sep 2020 19:33'	System	30 Sep 2020 23:33:16

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 6'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:46', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '36f58efe-c2e2-404a-916c-7893476f7f5d'	System	02 Oct 2020 00:47:58
User entered 'None (1)'	System	02 Oct 2020 00:47:58

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:48', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '36f58efe-c2e2-404a-916c-7893476f7f5d'	System	02 Oct 2020 00:47:58
User entered 'No (N)'	System	02 Oct 2020 00:47:58

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:51', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '36f58efe-c2e2-404a-916c-7893476f7f5d'	System	02 Oct 2020 00:47:58
User entered 'No (N)'	System	02 Oct 2020 00:47:58

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '36f58efe-c2e2-404a-916c-7893476f7f5d'	System	02 Oct 2020 00:47:58
User entered 'None (1)'	System	02 Oct 2020 00:47:58

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:55', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '36f58efe-c2e2-404a-916c-7893476f7f5d'	System	02 Oct 2020 00:47:58
User entered '01 Oct 2020 20:47'	System	02 Oct 2020 00:47:58

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 7'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:54:11', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e2fb06df-c160-4986-a16e-1e494aa98174'	System	03 Oct 2020 01:54:31
User entered 'None (1)'	System	03 Oct 2020 01:54:31

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:54:14', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e2fb06df-c160-4986-a16e-1e494aa98174'	System	03 Oct 2020 01:54:31
User entered 'No (N)'	System	03 Oct 2020 01:54:31

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:54:15', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e2fb06df-c160-4986-a16e-1e494aa98174'	System	03 Oct 2020 01:54:31
User entered 'No (N)'	System	03 Oct 2020 01:54:31

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:54:17', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e2fb06df-c160-4986-a16e-1e494aa98174'	System	03 Oct 2020 01:54:31
User entered 'None (1)'	System	03 Oct 2020 01:54:31

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:54:24', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e2fb06df-c160-4986-a16e-1e494aa98174'	System	03 Oct 2020 01:54:31
User entered '02 Oct 2020 21:54'	System	03 Oct 2020 01:54:31

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:43:51', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '75811f28-4cd6-4a6d-90fd-3320417e6cb3'	System	26 Sep 2020 14:45:36
User entered 'None (0)'	System	26 Sep 2020 14:45:36

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:43:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '75811f28-4cd6-4a6d-90fd-3320417e6cb3'	System	26 Sep 2020 14:45:36
User entered 'None (0)'	System	26 Sep 2020 14:45:36

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:44:05', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '75811f28-4cd6-4a6d-90fd-3320417e6cb3'	System	26 Sep 2020 14:45:36
User entered 'None (0)'	System	26 Sep 2020 14:45:36

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:44:07', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '75811f28-4cd6-4a6d-90fd-3320417e6cb3'	System	26 Sep 2020 14:45:36
User entered 'None (0)'	System	26 Sep 2020 14:45:36

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:44:09', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '75811f28-4cd6-4a6d-90fd-3320417e6cb3'	System	26 Sep 2020 14:45:36
User entered 'None (0)'	System	26 Sep 2020 14:45:36

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:44:10', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '75811f28-4cd6-4a6d-90fd-3320417e6cb3'	System	26 Sep 2020 14:45:36
User entered 'None (0)'	System	26 Sep 2020 14:45:36

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:44:17', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '75811f28-4cd6-4a6d-90fd-3320417e6cb3'	System	26 Sep 2020 14:45:36
User entered 'No (N)'	System	26 Sep 2020 14:45:36

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T10:45:31', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '75811f28-4cd6-4a6d-90fd-3320417e6cb3'	System	26 Sep 2020 14:45:36
User entered '26 Sep 2020 10:45'	System	26 Sep 2020 14:45:36

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '26 Sep 2020 10:18'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '26 Sep 2020 12:48'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:18:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4e9884c8-e2b8-4880-95b0-e5c97cbf6a75'	System	27 Sep 2020 00:19:17
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:19:17

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:18:57', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4e9884c8-e2b8-4880-95b0-e5c97cbf6a75'	System	27 Sep 2020 00:19:17
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:19:17

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:19:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4e9884c8-e2b8-4880-95b0-e5c97cbf6a75'	System	27 Sep 2020 00:19:17
User entered 'None (0)'	System	27 Sep 2020 00:19:17

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:19:02', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4e9884c8-e2b8-4880-95b0-e5c97cbf6a75'	System	27 Sep 2020 00:19:17
User entered 'None (0)'	System	27 Sep 2020 00:19:17

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:19:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4e9884c8-e2b8-4880-95b0-e5c97cbf6a75'	System	27 Sep 2020 00:19:17
User entered 'None (0)'	System	27 Sep 2020 00:19:17

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:19:06', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4e9884c8-e2b8-4880-95b0-e5c97cbf6a75'	System	27 Sep 2020 00:19:17
User entered 'None (0)'	System	27 Sep 2020 00:19:17

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:19:11', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4e9884c8-e2b8-4880-95b0-e5c97cbf6a75'	System	27 Sep 2020 00:19:17
User entered 'No (N)'	System	27 Sep 2020 00:19:17

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-26T20:19:14', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4e9884c8-e2b8-4880-95b0-e5c97cbf6a75'	System	27 Sep 2020 00:19:17
User entered '26 Sep 2020 20:19'	System	27 Sep 2020 00:19:17

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '26 Sep 2020 13:43'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 2'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:34:26', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '72f12c8d-72c8-4772-a38f-cd2956c97796'	System	27 Sep 2020 23:34:52
User entered 'No interference with activity (1)'	System	27 Sep 2020 23:34:52

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:34:30', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '72f12c8d-72c8-4772-a38f-cd2956c97796'	System	27 Sep 2020 23:34:52
User entered 'None (0)'	System	27 Sep 2020 23:34:52

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:34:32', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '72f12c8d-72c8-4772-a38f-cd2956c97796'	System	27 Sep 2020 23:34:52
User entered 'None (0)'	System	27 Sep 2020 23:34:52

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:34:35', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '72f12c8d-72c8-4772-a38f-cd2956c97796'	System	27 Sep 2020 23:34:52
User entered 'None (0)'	System	27 Sep 2020 23:34:52

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:34:37', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '72f12c8d-72c8-4772-a38f-cd2956c97796'	System	27 Sep 2020 23:34:52
User entered 'None (0)'	System	27 Sep 2020 23:34:52

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:34:39', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '72f12c8d-72c8-4772-a38f-cd2956c97796'	System	27 Sep 2020 23:34:52
User entered 'None (0)'	System	27 Sep 2020 23:34:52

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:34:43', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '72f12c8d-72c8-4772-a38f-cd2956c97796'	System	27 Sep 2020 23:34:52
User entered 'No (N)'	System	27 Sep 2020 23:34:52

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-27T19:34:50', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '72f12c8d-72c8-4772-a38f-cd2956c97796'	System	27 Sep 2020 23:34:52
User entered '27 Sep 2020 19:34'	System	27 Sep 2020 23:34:52

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 3'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:23', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6a089b9a-383f-4fd1-b982-968e3fd44c35'	System	28 Sep 2020 23:34:43
User entered 'None (0)'	System	28 Sep 2020 23:34:43

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:24', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6a089b9a-383f-4fd1-b982-968e3fd44c35'	System	28 Sep 2020 23:34:43
User entered 'None (0)'	System	28 Sep 2020 23:34:43

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:25', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6a089b9a-383f-4fd1-b982-968e3fd44c35'	System	28 Sep 2020 23:34:43
User entered 'None (0)'	System	28 Sep 2020 23:34:43

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:26', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6a089b9a-383f-4fd1-b982-968e3fd44c35'	System	28 Sep 2020 23:34:43
User entered 'None (0)'	System	28 Sep 2020 23:34:43

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:27', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6a089b9a-383f-4fd1-b982-968e3fd44c35'	System	28 Sep 2020 23:34:43
User entered 'None (0)'	System	28 Sep 2020 23:34:43

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:28', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6a089b9a-383f-4fd1-b982-968e3fd44c35'	System	28 Sep 2020 23:34:43
User entered 'None (0)'	System	28 Sep 2020 23:34:43

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:33', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6a089b9a-383f-4fd1-b982-968e3fd44c35'	System	28 Sep 2020 23:34:43
User entered 'No (N)'	System	28 Sep 2020 23:34:43

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-28T19:34:38', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6a089b9a-383f-4fd1-b982-968e3fd44c35'	System	28 Sep 2020 23:34:43
User entered '28 Sep 2020 19:34'	System	28 Sep 2020 23:34:43

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 4'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:58:49', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ae8ae740-dca0-4e0b-9089-053bafdbbd44'	System	30 Sep 2020 02:59:06
User entered 'None (0)'	System	30 Sep 2020 02:59:06

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:58:51', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ae8ae740-dca0-4e0b-9089-053bafdbbd44'	System	30 Sep 2020 02:59:06
User entered 'None (0)'	System	30 Sep 2020 02:59:06

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:58:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ae8ae740-dca0-4e0b-9089-053bafdbbd44'	System	30 Sep 2020 02:59:06
User entered 'None (0)'	System	30 Sep 2020 02:59:06

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:58:55', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ae8ae740-dca0-4e0b-9089-053bafdbbd44'	System	30 Sep 2020 02:59:06
User entered 'None (0)'	System	30 Sep 2020 02:59:06

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:58:56', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ae8ae740-dca0-4e0b-9089-053bafdbbd44'	System	30 Sep 2020 02:59:06
User entered 'None (0)'	System	30 Sep 2020 02:59:06

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:58:58', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ae8ae740-dca0-4e0b-9089-053bafdbbd44'	System	30 Sep 2020 02:59:06
User entered 'None (0)'	System	30 Sep 2020 02:59:06

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:59:01', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ae8ae740-dca0-4e0b-9089-053bafdbbd44'	System	30 Sep 2020 02:59:06
User entered 'No (N)'	System	30 Sep 2020 02:59:06

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-29T22:59:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ae8ae740-dca0-4e0b-9089-053bafdbbd44'	System	30 Sep 2020 02:59:06
User entered '29 Sep 2020 22:59'	System	30 Sep 2020 02:59:06

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 5'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:32:41', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bb0ecac4-0347-449f-815a-3699d7ce4617'	System	30 Sep 2020 23:32:57
User entered 'None (0)'	System	30 Sep 2020 23:32:57

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:32:42', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bb0ecac4-0347-449f-815a-3699d7ce4617'	System	30 Sep 2020 23:32:57
User entered 'None (0)'	System	30 Sep 2020 23:32:57

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:32:43', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bb0ecac4-0347-449f-815a-3699d7ce4617'	System	30 Sep 2020 23:32:57
User entered 'None (0)'	System	30 Sep 2020 23:32:57

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:32:44', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bb0ecac4-0347-449f-815a-3699d7ce4617'	System	30 Sep 2020 23:32:57
User entered 'None (0)'	System	30 Sep 2020 23:32:57

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:32:46', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bb0ecac4-0347-449f-815a-3699d7ce4617'	System	30 Sep 2020 23:32:57
User entered 'None (0)'	System	30 Sep 2020 23:32:57

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:32:47', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bb0ecac4-0347-449f-815a-3699d7ce4617'	System	30 Sep 2020 23:32:57
User entered 'None (0)'	System	30 Sep 2020 23:32:57

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:32:49', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bb0ecac4-0347-449f-815a-3699d7ce4617'	System	30 Sep 2020 23:32:57
User entered 'No (N)'	System	30 Sep 2020 23:32:57

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-09-30T19:32:54', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bb0ecac4-0347-449f-815a-3699d7ce4617'	System	30 Sep 2020 23:32:57
User entered '30 Sep 2020 19:32'	System	30 Sep 2020 23:32:57

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 6'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:28', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '3933c475-1c15-4bf5-b3cb-66243d5cff2b' User entered 'None (0)'	System	02 Oct 2020 00:47:45
	System	02 Oct 2020 00:47:45

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:30', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '3933c475-1c15-4bf5-b3cb-66243d5cff2b' User entered 'None (0)'	System	02 Oct 2020 00:47:45
	System	02 Oct 2020 00:47:45

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:31', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '3933c475-1c15-4bf5-b3cb-66243d5cff2b' User entered 'None (0)'	System	02 Oct 2020 00:47:45
	System	02 Oct 2020 00:47:45

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:32', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '3933c475-1c15-4bf5-b3cb-66243d5cff2b' User entered 'None (0)'	System	02 Oct 2020 00:47:45
	System	02 Oct 2020 00:47:45

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:33', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '3933c475-1c15-4bf5-b3cb-66243d5cff2b' User entered 'None (0)'	System	02 Oct 2020 00:47:45
	System	02 Oct 2020 00:47:45

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:34', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '3933c475-1c15-4bf5-b3cb-66243d5cff2b' User entered 'None (0)'	System	02 Oct 2020 00:47:45
	System	02 Oct 2020 00:47:45

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:38', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '3933c475-1c15-4bf5-b3cb-66243d5cff2b'	System	02 Oct 2020 00:47:45
User entered 'No (N)'	System	02 Oct 2020 00:47:45

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-01T20:47:42', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '3933c475-1c15-4bf5-b3cb-66243d5cff2b'	System	02 Oct 2020 00:47:45
User entered '01 Oct 2020 20:47'	System	02 Oct 2020 00:47:45

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	26 Sep 2020 14:11:48
User entered 'Day 7'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:53:54', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1a8aceb7-7203-4ed6-aa1f-6d90263e5a69'	System	03 Oct 2020 01:54:13
User entered 'None (0)'	System	03 Oct 2020 01:54:13

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:53:55', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1a8aceb7-7203-4ed6-aa1f-6d90263e5a69'	System	03 Oct 2020 01:54:13
User entered 'None (0)'	System	03 Oct 2020 01:54:13

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:53:56', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1a8aceb7-7203-4ed6-aa1f-6d90263e5a69'	System	03 Oct 2020 01:54:13
User entered 'None (0)'	System	03 Oct 2020 01:54:13

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:53:58', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1a8aceb7-7203-4ed6-aa1f-6d90263e5a69'	System	03 Oct 2020 01:54:13
User entered 'None (0)'	System	03 Oct 2020 01:54:13

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:53:59', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1a8aceb7-7203-4ed6-aa1f-6d90263e5a69'	System	03 Oct 2020 01:54:13
User entered 'None (0)'	System	03 Oct 2020 01:54:13

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:54:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1a8aceb7-7203-4ed6-aa1f-6d90263e5a69'	System	03 Oct 2020 01:54:13
User entered 'None (0)'	System	03 Oct 2020 01:54:13

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:54:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1a8aceb7-7203-4ed6-aa1f-6d90263e5a69'	System	03 Oct 2020 01:54:13
User entered 'No (N)'	System	03 Oct 2020 01:54:13

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-02T21:54:08', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1a8aceb7-7203-4ed6-aa1f-6d90263e5a69'	System	03 Oct 2020 01:54:13
User entered '02 Oct 2020 21:54'	System	03 Oct 2020 01:54:13

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 14:11:48

US3742463

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 14:11:48

US3742463

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	06 Oct 2020 13:43:38

US3742463

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '3 Oct 2020'	Sherry McCammon (b) (4)	06 Oct 2020 13:43:38

US3742463

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	06 Oct 2020 13:43:38

US3742463

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	Sherry McCammon (b) (4)	06 Oct 2020 13:43:38

US3742463

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	06 Oct 2020 13:43:42

US3742463

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'I'	System	06 Oct 2020 13:43:42

US3742463

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	12 Oct 2020 15:26:18

US3742463

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '10 Oct 2020'	Sherry McCammon (b) (4)	12 Oct 2020 15:26:18

US3742463

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	12 Oct 2020 15:26:18

US3742463

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	Sherry McCammon (b) (4)	12 Oct 2020 15:26:18

US3742463

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	12 Oct 2020 15:27:04

US3742463

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'I'	System	12 Oct 2020 15:27:04

US3742463

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	Toni Robinson (b) (4)	19 Oct 2020 14:16:59

US3742463

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '19 Oct 2020'	Toni Robinson (b) (4)	19 Oct 2020 14:16:59

US3742463

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Contact Made (CONTACT MADE)'	Toni Robinson (b) (4)	19 Oct 2020 14:16:59

US3742463

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	Toni Robinson (b) (4)	19 Oct 2020 14:16:59

US3742463

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:20:22

US3742463

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'I'	System	27 Oct 2020 12:20:22

US3742463

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:21:37

US3742463

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:21:37

US3742463

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Home (Home)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:21:37

US3742463

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'VISIT2'	System	27 Oct 2020 12:21:37

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20
	(b) (4)	

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '27 Oct 2020'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '07:26'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '27 Oct 2020 07:26'	System	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '097.5' F	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '055'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'bpm'	System	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '14'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'breaths/min'	System	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '123'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'mmHg'	System	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '076'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'mmHg'	System	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20
	(b) (4)	

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '27 Oct 2020'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '08:54'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '27 Oct 2020 08:54'	System	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '098.5' F	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Oral (Oral)'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '055'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'bpm'	System	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '16'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'breaths/min'	System	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '123'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'mmHg'	System	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '081'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'mmHg'	System	27 Oct 2020 13:17:20

US3742463

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:22:13

US3742463

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:22

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:22:13

US3742463

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:38

US3742463

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:38

US3742463

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:38

US3742463

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:38

US3742463

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:38

US3742463

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:38

US3742463

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '07:50'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:38

US3742463

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '27 Oct 2020 07:50'	System	27 Oct 2020 12:24:38

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:20:59

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:20:59

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:20:59

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'MRNA-1273 OR PLACEBO'	System	27 Oct 2020 12:20:59

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:20:59

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '08:12'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:20:59

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '27 Oct 2020 08:12'	System	27 Oct 2020 12:20:59

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:20:59

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'ONCE'	System	27 Oct 2020 12:20:59

US3742463

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:22:22

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'INTRAMUSCULAR'	System	27 Oct 2020 12:20:59

US3742463

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:56

US3742463

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:56

US3742463

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '07:37'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:24:56

US3742463

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '27 Oct 2020 07:37'	System	27 Oct 2020 12:24:56

US3742463

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:22:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:25:17

US3742463

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	27 Oct 2020 12:25:17

US3742463

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:25:17

US3742463

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '07:50'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:25:17

US3742463

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '27 Oct 2020 07:50'	System	27 Oct 2020 12:25:17

US3742463

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:22

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	27 Oct 2020 12:25:17

US3742463

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:25:17

US3742463

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:25:17

US3742463

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered empty.	System	27 Oct 2020 12:25:17

US3742463

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	27 Oct 2020 13:17:27

US3742463

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '1'	System	27 Oct 2020 13:17:27

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:46:57', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f071f351-a239-43fd-86ed-854663e56e3d'	System	27 Oct 2020 12:50:22
User entered 'Yes (Y)'	System	27 Oct 2020 12:50:22

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:50:09', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f071f351-a239-43fd-86ed-854663e56e3d'	System	27 Oct 2020 12:50:22
User entered '98.5'	System	27 Oct 2020 12:50:22

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:50:11', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f071f351-a239-43fd-86ed-854663e56e3d'	System	27 Oct 2020 12:50:22
User entered 'No (N)'	System	27 Oct 2020 12:50:22

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:50:18', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f071f351-a239-43fd-86ed-854663e56e3d'	System	27 Oct 2020 12:50:22
User entered '27 Oct 2020 08:50'	System	27 Oct 2020 12:50:22

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Oct 2020 08:32'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Oct 2020 11:02'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:43:23', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b9641d2d-8ef9-4104-868e-5bbbbb93bc2'	System	28 Oct 2020 00:43:56
User entered 'Yes (Y)'	System	28 Oct 2020 00:43:56

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:43:27', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b9641d2d-8ef9-4104-868e-5bbbbb93bc2'	System	28 Oct 2020 00:43:56
User entered '100.0'	System	28 Oct 2020 00:43:56

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:43:31', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b9641d2d-8ef9-4104-868e-5bbbbb93bc2'	System	28 Oct 2020 00:43:56
User entered 'Yes (Y)'	System	28 Oct 2020 00:43:56

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
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). 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 'IBUPROFEN 200 MG ONCE' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 05:32:03
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:43:36', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b9641d2d-8ef9-4104-868e-5bbbbb93bc2'	(b) (4), (b) (6)	03 Nov 2020 14:36:59
User entered '1'	System	28 Oct 2020 00:43:56
	System	28 Oct 2020 00:43:56
	System	28 Oct 2020 00:43:56

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:43:36', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b9641d2d-8ef9-4104-868e-5bbbbbe93bc2'	System	28 Oct 2020 00:43:56
User entered '0'	System	28 Oct 2020 00:43:56

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:43:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b9641d2d-8ef9-4104-868e-5bbbbb93bc2'	System	28 Oct 2020 00:43:56
User entered '27 Oct 2020 20:43'	System	28 Oct 2020 00:43:56

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Oct 2020 11:57'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 2'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:11:34', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '919a1ded-09eb-4d45-a50a-b0effe2ecd0a'	System	29 Oct 2020 00:13:39
User entered 'Yes (Y)'	System	29 Oct 2020 00:13:39

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:13:26', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '919a1ded-09eb-4d45-a50a-b0effe2ecd0a'	System	29 Oct 2020 00:13:39
User entered '98.2'	System	29 Oct 2020 00:13:39

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:13:29', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '919a1ded-09eb-4d45-a50a-b0effe2ecd0a'	System	29 Oct 2020 00:13:39
User entered 'Yes (Y)'	System	29 Oct 2020 00:13:39

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
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). 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 'TYLENOL 1000 MG PO ONCE' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 05:59:58
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).	(b) (4), (b) (6)	03 Nov 2020 14:49:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:13:32', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '919a1ded-09eb-4d45-a50a-b0effe2ecd0a'	System	29 Oct 2020 00:13:39
User entered '1'	System	29 Oct 2020 00:13:39

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:13:32', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '919a1ded-09eb-4d45-a50a-b0effe2ecd0a' User entered '0'	System	29 Oct 2020 00:13:39
	System	29 Oct 2020 00:13:39

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:13:36', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '919a1ded-09eb-4d45-a50a-b0effe2ecd0a'	System	29 Oct 2020 00:13:39
User entered '28 Oct 2020 20:13'	System	29 Oct 2020 00:13:39

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 3'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:17:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '16dbf595-d1e0-4a64-a146-67597992f7b1'	System	30 Oct 2020 02:17:21
User entered 'Yes (Y)'	System	30 Oct 2020 02:17:21

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:17:12', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '16dbf595-d1e0-4a64-a146-67597992f7b1' User entered '97.4'	System	30 Oct 2020 02:17:21
	System	30 Oct 2020 02:17:21

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:17:14', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '16dbf595-d1e0-4a64-a146-67597992f7b1'	System	30 Oct 2020 02:17:21
User entered 'No (N)'	System	30 Oct 2020 02:17:21

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:17:17', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '16dbf595-d1e0-4a64-a146-67597992f7b1' User entered '29 Oct 2020 22:17'	System	30 Oct 2020 02:17:21
	System	30 Oct 2020 02:17:21

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 4'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T11:38:08', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '62bb4eb0-3eb3-413e-ba3e-3da32a018fbc'	System	31 Oct 2020 15:38:18
User entered 'No (N)'	System	31 Oct 2020 15:38:18

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T11:38:12', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '62bb4eb0-3eb3-413e-ba3e-3da32a018fbc'	System	31 Oct 2020 15:38:18
User entered 'No (N)'	System	31 Oct 2020 15:38:18

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T11:38:14', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '62bb4eb0-3eb3-413e-ba3e-3da32a018fbc'	System	31 Oct 2020 15:38:18
User entered '31 Oct 2020 11:38'	System	31 Oct 2020 15:38:18

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 5'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:14:13', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e313a190-9e67-437b-92c2-96edc8cdefae'	System	01 Nov 2020 01:14:35
User entered 'Yes (Y)'	System	01 Nov 2020 01:14:35

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:14:25', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e313a190-9e67-437b-92c2-96edc8cdefae' User entered '96.5'	System	01 Nov 2020 01:14:35
	System	01 Nov 2020 01:14:35

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:14:28', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e313a190-9e67-437b-92c2-96edc8cdefae'	System	01 Nov 2020 01:14:35
User entered 'No (N)'	System	01 Nov 2020 01:14:35

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:14:31', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e313a190-9e67-437b-92c2-96edc8cdefae'	System	01 Nov 2020 01:14:35
User entered '31 Oct 2020 21:14'	System	01 Nov 2020 01:14:35

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 6'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:46:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '813abdde-300a-4388-80ae-e9b577576b3a'	System	02 Nov 2020 02:46:31
User entered 'Yes (Y)'	System	02 Nov 2020 02:46:31

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:46:22', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '813abdde-300a-4388-80ae-e9b577576b3a'	System	02 Nov 2020 02:46:31
User entered '97.6'	System	02 Nov 2020 02:46:31

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:46:24', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '813abdde-300a-4388-80ae-e9b577576b3a'	System	02 Nov 2020 02:46:31
User entered 'No (N)'	System	02 Nov 2020 02:46:31

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:46:29', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '813abdde-300a-4388-80ae-e9b577576b3a'	System	02 Nov 2020 02:46:31
User entered '01 Nov 2020 21:46'	System	02 Nov 2020 02:46:31

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 7'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:21:44', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '8476961b-d571-4ef8-9ceb-64409e9687d6'	System	03 Nov 2020 03:21:54
User entered 'Yes (Y)'	System	03 Nov 2020 03:21:54

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:21:47', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '8476961b-d571-4ef8-9ceb-64409e9687d6' User entered '97.0'	System	03 Nov 2020 03:21:54
	System	03 Nov 2020 03:21:54

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:21:49', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '8476961b-d571-4ef8-9ceb-64409e9687d6'	System	03 Nov 2020 03:21:54
User entered 'No (N)'	System	03 Nov 2020 03:21:54

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:21:50', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '8476961b-d571-4ef8-9ceb-64409e9687d6'	System	03 Nov 2020 03:21:54
User entered '02 Nov 2020 22:21'	System	03 Nov 2020 03:21:54

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:46:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'cc716362-b736-430b-afe2-924500fe9e90'	System	27 Oct 2020 12:46:45
User entered 'None (1)'	System	27 Oct 2020 12:46:45

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:46:07', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'cc716362-b736-430b-afe2-924500fe9e90'	System	27 Oct 2020 12:46:45
User entered 'No (N)'	System	27 Oct 2020 12:46:45

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:46:09', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'cc716362-b736-430b-afe2-924500fe9e90'	System	27 Oct 2020 12:46:45
User entered 'No (N)'	System	27 Oct 2020 12:46:45

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:46:20', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'cc716362-b736-430b-afe2-924500fe9e90'	System	27 Oct 2020 12:46:45
User entered 'None (1)'	System	27 Oct 2020 12:46:45

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:46:41', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'cc716362-b736-430b-afe2-924500fe9e90'	System	27 Oct 2020 12:46:45
User entered '27 Oct 2020 08:46'	System	27 Oct 2020 12:46:45

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Oct 2020 08:32'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Oct 2020 11:02'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:40:25', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'defce35c-c0a7-4738-8978-c512ba3259ed'	System	28 Oct 2020 00:41:15
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		28 Oct 2020 00:41:15

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:40:27', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'defce35c-c0a7-4738-8978-c512ba3259ed'	System	28 Oct 2020 00:41:15
User entered 'No (N)'	System	28 Oct 2020 00:41:15

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:40:40', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'defce35c-c0a7-4738-8978-c512ba3259ed'	System	28 Oct 2020 00:41:15
User entered 'No (N)'	System	28 Oct 2020 00:41:15

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:40:49', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'defce35c-c0a7-4738-8978-c512ba3259ed'	System	28 Oct 2020 00:41:15
User entered 'None (1)'	System	28 Oct 2020 00:41:15

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:41:11', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'defce35c-c0a7-4738-8978-c512ba3259ed'	System	28 Oct 2020 00:41:15
User entered '27 Oct 2020 20:41'	System	28 Oct 2020 00:41:15

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Oct 2020 11:57'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 2'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '261bdbbd-db21-45b6-be00-e2d27bea237a'	System	29 Oct 2020 00:12:11
User entered 'Does not interfere with activity (2)'	System	29 Oct 2020 00:12:11

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:02', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '261bdbbd-db21-45b6-be00-e2d27bea237a'	System	29 Oct 2020 00:12:11
User entered 'No (N)'	System	29 Oct 2020 00:12:11

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '261bdbbd-db21-45b6-be00-e2d27bea237a'	System	29 Oct 2020 00:12:11
User entered 'No (N)'	System	29 Oct 2020 00:12:11

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:05', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '261bdbbd-db21-45b6-be00-e2d27bea237a'	System	29 Oct 2020 00:12:11
User entered 'None (1)'	System	29 Oct 2020 00:12:11

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:09', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '261bdbbd-db21-45b6-be00-e2d27bea237a'	System	29 Oct 2020 00:12:11
User entered '28 Oct 2020 20:12'	System	29 Oct 2020 00:12:11

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 3'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:50', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'c8f6174b-1fbe-4504-a89c-b9f403113eac'	System	30 Oct 2020 02:17:02
User entered 'Does not interfere with activity (2)'	System	30 Oct 2020 02:17:02

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:52', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'c8f6174b-1fbe-4504-a89c-b9f403113eac'	System	30 Oct 2020 02:17:02
User entered 'No (N)'	System	30 Oct 2020 02:17:02

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:54', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'c8f6174b-1fbe-4504-a89c-b9f403113eac'	System	30 Oct 2020 02:17:02
User entered 'No (N)'	System	30 Oct 2020 02:17:02

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:56', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'c8f6174b-1fbe-4504-a89c-b9f403113eac'	System	30 Oct 2020 02:17:02
User entered 'None (1)'	System	30 Oct 2020 02:17:02

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:59', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'c8f6174b-1fbe-4504-a89c-b9f403113eac'	System	30 Oct 2020 02:17:02
User entered '29 Oct 2020 22:16'	System	30 Oct 2020 02:17:02

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 4'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:13:40', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'd2f6cfed-fb6f-4225-9a08-1ea34779c07e'	System	31 Oct 2020 10:13:54
User entered 'None (1)'	System	31 Oct 2020 10:13:54

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:13:42', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'd2f6cfed-fb6f-4225-9a08-1ea34779c07e'	System	31 Oct 2020 10:13:54
User entered 'No (N)'	System	31 Oct 2020 10:13:54

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:13:45', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'd2f6cfed-fb6f-4225-9a08-1ea34779c07e'	System	31 Oct 2020 10:13:54
User entered 'No (N)'	System	31 Oct 2020 10:13:54

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:13:48', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'd2f6cfed-fb6f-4225-9a08-1ea34779c07e'	System	31 Oct 2020 10:13:54
User entered 'None (1)'	System	31 Oct 2020 10:13:54

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:13:52', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'd2f6cfed-fb6f-4225-9a08-1ea34779c07e'	System	31 Oct 2020 10:13:54
User entered '31 Oct 2020 06:13'	System	31 Oct 2020 10:13:54

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 5'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:48', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b70d0a68-a9c7-4de4-b022-0bb0ebc17a30'	System	01 Nov 2020 01:14:05
User entered 'None (1)'	System	01 Nov 2020 01:14:05

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:51', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b70d0a68-a9c7-4de4-b022-0bb0ebc17a30'	System	01 Nov 2020 01:14:05
User entered 'No (N)'	System	01 Nov 2020 01:14:05

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:55', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b70d0a68-a9c7-4de4-b022-0bb0ebc17a30'	System	01 Nov 2020 01:14:05
User entered 'No (N)'	System	01 Nov 2020 01:14:05

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:57', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b70d0a68-a9c7-4de4-b022-0bb0ebc17a30'	System	01 Nov 2020 01:14:05
User entered 'None (1)'	System	01 Nov 2020 01:14:05

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:14:01', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b70d0a68-a9c7-4de4-b022-0bb0ebc17a30'	System	01 Nov 2020 01:14:05
User entered '31 Oct 2020 21:14'	System	01 Nov 2020 01:14:05

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 6'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:38', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b6852888-015b-495b-ad02-29bd78f50286'	System	02 Nov 2020 02:45:57
User entered 'None (1)'	System	02 Nov 2020 02:45:57

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:41', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b6852888-015b-495b-ad02-29bd78f50286'	System	02 Nov 2020 02:45:57
User entered 'No (N)'	System	02 Nov 2020 02:45:57

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:42', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b6852888-015b-495b-ad02-29bd78f50286'	System	02 Nov 2020 02:45:57
User entered 'No (N)'	System	02 Nov 2020 02:45:57

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:48', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b6852888-015b-495b-ad02-29bd78f50286'	System	02 Nov 2020 02:45:57
User entered 'None (1)'	System	02 Nov 2020 02:45:57

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:51', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b6852888-015b-495b-ad02-29bd78f50286'	System	02 Nov 2020 02:45:57
User entered '01 Nov 2020 21:45'	System	02 Nov 2020 02:45:57

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 7'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:27', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '018e7619-91f6-46a2-937a-fabc6625ea52'	System	03 Nov 2020 03:22:44
User entered 'None (1)'	System	03 Nov 2020 03:22:44

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:29', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '018e7619-91f6-46a2-937a-fabc6625ea52'	System	03 Nov 2020 03:22:44
User entered 'No (N)'	System	03 Nov 2020 03:22:44

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:30', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '018e7619-91f6-46a2-937a-fabc6625ea52'	System	03 Nov 2020 03:22:44
User entered 'No (N)'	System	03 Nov 2020 03:22:44

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:32', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '018e7619-91f6-46a2-937a-fabc6625ea52'	System	03 Nov 2020 03:22:44
User entered 'None (1)'	System	03 Nov 2020 03:22:44

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:37', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '018e7619-91f6-46a2-937a-fabc6625ea52'	System	03 Nov 2020 03:22:44
User entered '02 Nov 2020 22:22'	System	03 Nov 2020 03:22:44

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:45:52', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1f2c0068-78d2-4bde-8a7c-0e9008ce4044'	System	27 Oct 2020 12:46:02
User entered 'None (0)'	System	27 Oct 2020 12:46:02

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:45:19', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1f2c0068-78d2-4bde-8a7c-0e9008ce4044'	System	27 Oct 2020 12:46:02
User entered 'None (0)'	System	27 Oct 2020 12:46:02

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:45:24', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1f2c0068-78d2-4bde-8a7c-0e9008ce4044'	System	27 Oct 2020 12:46:02
User entered 'None (0)'	System	27 Oct 2020 12:46:02

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:45:35', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1f2c0068-78d2-4bde-8a7c-0e9008ce4044'	System	27 Oct 2020 12:46:02
User entered 'None (0)'	System	27 Oct 2020 12:46:02

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:45:37', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1f2c0068-78d2-4bde-8a7c-0e9008ce4044'	System	27 Oct 2020 12:46:02
User entered 'None (0)'	System	27 Oct 2020 12:46:02

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:45:41', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1f2c0068-78d2-4bde-8a7c-0e9008ce4044'	System	27 Oct 2020 12:46:02
User entered 'None (0)'	System	27 Oct 2020 12:46:02

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:45:44', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1f2c0068-78d2-4bde-8a7c-0e9008ce4044'	System	27 Oct 2020 12:46:02
User entered 'No (N)'	System	27 Oct 2020 12:46:02

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T08:45:59', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1f2c0068-78d2-4bde-8a7c-0e9008ce4044'	System	27 Oct 2020 12:46:02
User entered '27 Oct 2020 08:45'	System	27 Oct 2020 12:46:02

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Oct 2020 08:32'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Oct 2020 11:02'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:39:28', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b868e836-97f7-4860-aba4-e0cd7646df46'	System	28 Oct 2020 00:40:17
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		28 Oct 2020 00:40:17

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:39:32', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b868e836-97f7-4860-aba4-e0cd7646df46'	System	28 Oct 2020 00:40:17
User entered 'Significant; prevents daily activity (3)'	System	28 Oct 2020 00:40:17

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:39:40', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b868e836-97f7-4860-aba4-e0cd7646df46'	System	28 Oct 2020 00:40:17
User entered 'None (0)'	System	28 Oct 2020 00:40:17

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:39:43', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b868e836-97f7-4860-aba4-e0cd7646df46'	System	28 Oct 2020 00:40:17
User entered 'None (0)'	System	28 Oct 2020 00:40:17

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:39:47', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b868e836-97f7-4860-aba4-e0cd7646df46'	System	28 Oct 2020 00:40:17
User entered 'None (0)'	System	28 Oct 2020 00:40:17

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:39:54', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b868e836-97f7-4860-aba4-e0cd7646df46'	System	28 Oct 2020 00:40:17
User entered 'Some interference with activity not requiring medical attention (2)'	System	28 Oct 2020 00:40:17

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:39:58', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b868e836-97f7-4860-aba4-e0cd7646df46'	System	28 Oct 2020 00:40:17
User entered 'No (N)'	System	28 Oct 2020 00:40:17

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-27T20:40:13', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b868e836-97f7-4860-aba4-e0cd7646df46'	System	28 Oct 2020 00:40:17
User entered '27 Oct 2020 20:40'	System	28 Oct 2020 00:40:17

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '27 Oct 2020 11:57'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 2'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:13', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f729d274-e13c-4f38-9465-756801dbf65b'	System	29 Oct 2020 00:13:09
User entered 'No interference with activity (1)'	System	29 Oct 2020 00:13:09

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:37', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f729d274-e13c-4f38-9465-756801dbf65b'	System	29 Oct 2020 00:13:09
User entered 'Some interference with activity (2)'	System	29 Oct 2020 00:13:09

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:40', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f729d274-e13c-4f38-9465-756801dbf65b'	System	29 Oct 2020 00:13:09
User entered 'Some interference with activity (2)'	System	29 Oct 2020 00:13:09

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:44', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f729d274-e13c-4f38-9465-756801dbf65b'	System	29 Oct 2020 00:13:09
User entered 'None (0)'	System	29 Oct 2020 00:13:09

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:13:02', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f729d274-e13c-4f38-9465-756801dbf65b'	System	29 Oct 2020 00:13:09
User entered 'None (0)'	System	29 Oct 2020 00:13:09

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:52', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f729d274-e13c-4f38-9465-756801dbf65b'	System	29 Oct 2020 00:13:09
User entered 'None (0)'	System	29 Oct 2020 00:13:09

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:12:55', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f729d274-e13c-4f38-9465-756801dbf65b'	System	29 Oct 2020 00:13:09
User entered 'No (N)'	System	29 Oct 2020 00:13:09

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-28T20:13:05', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'f729d274-e13c-4f38-9465-756801dbf65b'	System	29 Oct 2020 00:13:09
User entered '28 Oct 2020 20:13'	System	29 Oct 2020 00:13:09

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 3'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:26', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2db7fdbb-5e8f-4902-883f-6a82650bf6f4'	System	30 Oct 2020 02:16:45
User entered 'None (0)'	System	30 Oct 2020 02:16:45

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:28', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2db7fdbb-5e8f-4902-883f-6a82650bf6f4'	System	30 Oct 2020 02:16:45
User entered 'None (0)'	System	30 Oct 2020 02:16:45

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:31', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2db7fdbb-5e8f-4902-883f-6a82650bf6f4'	System	30 Oct 2020 02:16:45
User entered 'None (0)'	System	30 Oct 2020 02:16:45

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:32', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2db7fdbb-5e8f-4902-883f-6a82650bf6f4'	System	30 Oct 2020 02:16:45
User entered 'None (0)'	System	30 Oct 2020 02:16:45

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:35', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2db7fdbb-5e8f-4902-883f-6a82650bf6f4'	System	30 Oct 2020 02:16:45
User entered 'None (0)'	System	30 Oct 2020 02:16:45

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:36', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2db7fdbb-5e8f-4902-883f-6a82650bf6f4'	System	30 Oct 2020 02:16:45
User entered 'None (0)'	System	30 Oct 2020 02:16:45

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:38', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2db7fdbb-5e8f-4902-883f-6a82650bf6f4'	System	30 Oct 2020 02:16:45
User entered 'No (N)'	System	30 Oct 2020 02:16:45

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-29T22:16:40', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2db7fdbb-5e8f-4902-883f-6a82650bf6f4'	System	30 Oct 2020 02:16:45
User entered '29 Oct 2020 22:16'	System	30 Oct 2020 02:16:45

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 4'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:13:57', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bc782bbc-546d-4b70-970a-858b94a11fba'	System	31 Oct 2020 10:14:23
User entered 'None (0)'	System	31 Oct 2020 10:14:23

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:14:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bc782bbc-546d-4b70-970a-858b94a11fba'	System	31 Oct 2020 10:14:23
User entered 'None (0)'	System	31 Oct 2020 10:14:23

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:14:02', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bc782bbc-546d-4b70-970a-858b94a11fba'	System	31 Oct 2020 10:14:23
User entered 'None (0)'	System	31 Oct 2020 10:14:23

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:14:05', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bc782bbc-546d-4b70-970a-858b94a11fba'	System	31 Oct 2020 10:14:23
User entered 'None (0)'	System	31 Oct 2020 10:14:23

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:14:07', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bc782bbc-546d-4b70-970a-858b94a11fba'	System	31 Oct 2020 10:14:23
User entered 'None (0)'	System	31 Oct 2020 10:14:23

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:14:10', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bc782bbc-546d-4b70-970a-858b94a11fba'	System	31 Oct 2020 10:14:23
User entered 'None (0)'	System	31 Oct 2020 10:14:23

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:14:12', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bc782bbc-546d-4b70-970a-858b94a11fba'	System	31 Oct 2020 10:14:23
User entered 'No (N)'	System	31 Oct 2020 10:14:23

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T06:14:18', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bc782bbc-546d-4b70-970a-858b94a11fba'	System	31 Oct 2020 10:14:23
User entered '31 Oct 2020 06:14'	System	31 Oct 2020 10:14:23

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 5'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:25', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9454794d-ee49-45e2-b493-e80dc2f4d861'	System	01 Nov 2020 01:13:49
User entered 'None (0)'	System	01 Nov 2020 01:13:49

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:28', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9454794d-ee49-45e2-b493-e80dc2f4d861'	System	01 Nov 2020 01:13:49
User entered 'None (0)'	System	01 Nov 2020 01:13:49

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:30', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9454794d-ee49-45e2-b493-e80dc2f4d861'	System	01 Nov 2020 01:13:49
User entered 'None (0)'	System	01 Nov 2020 01:13:49

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:35', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9454794d-ee49-45e2-b493-e80dc2f4d861'	System	01 Nov 2020 01:13:49
User entered 'None (0)'	System	01 Nov 2020 01:13:49

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:36', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9454794d-ee49-45e2-b493-e80dc2f4d861'	System	01 Nov 2020 01:13:49
User entered 'None (0)'	System	01 Nov 2020 01:13:49

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:38', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9454794d-ee49-45e2-b493-e80dc2f4d861'	System	01 Nov 2020 01:13:49
User entered 'None (0)'	System	01 Nov 2020 01:13:49

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:39', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9454794d-ee49-45e2-b493-e80dc2f4d861'	System	01 Nov 2020 01:13:49
User entered 'No (N)'	System	01 Nov 2020 01:13:49

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-10-31T21:13:43', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9454794d-ee49-45e2-b493-e80dc2f4d861'	System	01 Nov 2020 01:13:49
User entered '31 Oct 2020 21:13'	System	01 Nov 2020 01:13:49

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 6'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:20', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a52ee4b8-699b-4c61-a5d5-7940d11cdee6'	System	02 Nov 2020 02:45:37
User entered 'None (0)'	System	02 Nov 2020 02:45:37

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:22', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a52ee4b8-699b-4c61-a5d5-7940d11cdee6'	System	02 Nov 2020 02:45:37
User entered 'None (0)'	System	02 Nov 2020 02:45:37

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:23', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a52ee4b8-699b-4c61-a5d5-7940d11cdee6'	System	02 Nov 2020 02:45:37
User entered 'None (0)'	System	02 Nov 2020 02:45:37

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:25', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a52ee4b8-699b-4c61-a5d5-7940d11cdee6'	System	02 Nov 2020 02:45:37
User entered 'None (0)'	System	02 Nov 2020 02:45:37

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:27', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a52ee4b8-699b-4c61-a5d5-7940d11cdee6'	System	02 Nov 2020 02:45:37
User entered 'None (0)'	System	02 Nov 2020 02:45:37

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:30', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a52ee4b8-699b-4c61-a5d5-7940d11cdee6'	System	02 Nov 2020 02:45:37
User entered 'None (0)'	System	02 Nov 2020 02:45:37

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:32', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a52ee4b8-699b-4c61-a5d5-7940d11cdee6'	System	02 Nov 2020 02:45:37
User entered 'No (N)'	System	02 Nov 2020 02:45:37

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-01T21:45:34', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a52ee4b8-699b-4c61-a5d5-7940d11cdee6'	System	02 Nov 2020 02:45:37
User entered '01 Nov 2020 21:45'	System	02 Nov 2020 02:45:37

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
Data entry locked.	System	27 Oct 2020 12:20:59
User entered 'Day 7'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:21:54', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e452b085-fac5-48a6-a5b5-904072b46fae'	System	03 Nov 2020 03:22:28
User entered 'None (0)'	System	03 Nov 2020 03:22:28

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:21:58', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e452b085-fac5-48a6-a5b5-904072b46fae'	System	03 Nov 2020 03:22:28
User entered 'None (0)'	System	03 Nov 2020 03:22:28

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:05', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e452b085-fac5-48a6-a5b5-904072b46fae'	System	03 Nov 2020 03:22:28
User entered 'None (0)'	System	03 Nov 2020 03:22:28

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:09', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e452b085-fac5-48a6-a5b5-904072b46fae'	System	03 Nov 2020 03:22:28
User entered 'None (0)'	System	03 Nov 2020 03:22:28

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:14', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e452b085-fac5-48a6-a5b5-904072b46fae'	System	03 Nov 2020 03:22:28
User entered 'None (0)'	System	03 Nov 2020 03:22:28

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:17', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e452b085-fac5-48a6-a5b5-904072b46fae'	System	03 Nov 2020 03:22:28
User entered 'None (0)'	System	03 Nov 2020 03:22:28

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:21', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e452b085-fac5-48a6-a5b5-904072b46fae'	System	03 Nov 2020 03:22:28
User entered 'No (N)'	System	03 Nov 2020 03:22:28

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3eb05466d95ded6d)', Time: '2020-11-02T22:22:24', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'e452b085-fac5-48a6-a5b5-904072b46fae'	System	03 Nov 2020 03:22:28
User entered '02 Nov 2020 22:22'	System	03 Nov 2020 03:22:28

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 12:20:59

US3742463

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:22:22

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 14:59:29
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 12:20:59

US3742463

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	Hassan Haji (b) (4)	04 Nov 2020 14:25:59

US3742463

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '4 Nov 2020'	Hassan Haji (b) (4)	04 Nov 2020 14:25:59

US3742463

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	04 Nov 2020 14:25:59

US3742463

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	Hassan Haji (b) (4)	04 Nov 2020 14:25:59

US3742463

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	Hassan Haji (b) (4)	04 Nov 2020 14:26:30

US3742463

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'I'	System	04 Nov 2020 14:26:30

US3742463

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	Hassan Haji (b) (4)	10 Nov 2020 15:44:58

US3742463

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '10 Nov 2020'	Hassan Haji (b) (4)	10 Nov 2020 15:44:58

US3742463

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	10 Nov 2020 15:44:58

US3742463

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	Hassan Haji (b) (4)	10 Nov 2020 15:44:58

US3742463

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	Hassan Haji (b) (4)	10 Nov 2020 15:45:22

US3742463

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'I'	System	10 Nov 2020 15:45:22

US3742463

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:43:27

US3742463

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered '17 Nov 2020'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:43:27

US3742463

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:43:27

US3742463

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:43:27

US3742463

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:43:31

US3742463

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'I'	System	17 Nov 2020 14:43:31

US3742463

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:54:43

US3742463

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '21 Nov 2020'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:54:43

US3742463

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:54:43

US3742463

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'VISIT3'	System	21 Nov 2020 13:54:43

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered empty.	System	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered empty.	System	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered empty.	System	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered empty.	System	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered empty.	System	21 Nov 2020 13:56:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26

US3742463

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26

US3742463

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:55:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:55:11

US3742463

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:55:57

US3742463

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '21 Nov 2020'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:55:57

US3742463

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered '08:25'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:55:57

US3742463

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '21 Nov 2020 08:25'	System	21 Nov 2020 13:55:57

US3742463

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:57:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Nov 2020 13:56:21

US3742463

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered '1'	System	21 Nov 2020 13:56:21

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-11-24T09:47:25', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a250520c-b66c-4836-a56c-bb9c29d62179' User entered 'No (N)'	System	24 Nov 2020 14:47:36
	System	24 Nov 2020 14:47:36

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-11-24T09:47:30', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a250520c-b66c-4836-a56c-bb9c29d62179' User entered 'No (N)'	System	24 Nov 2020 14:47:36

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-11-24T09:47:33', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a250520c-b66c-4836-a56c-bb9c29d62179' User entered '24 Nov 2020 09:47:33'	System	24 Nov 2020 14:47:36
	System	24 Nov 2020 14:47:36

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-11-30T12:19:18', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '786cf5e7-0071-4ade-9010-e3be52806e0e' User entered 'No (N)'	System	30 Nov 2020 17:19:32

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-11-30T12:19:26', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '786cf5e7-0071-4ade-9010-e3be52806e0e' User entered 'No (N)'	System	30 Nov 2020 17:19:32

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-11-30T12:19:28', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '786cf5e7-0071-4ade-9010-e3be52806e0e' User entered '30 Nov 2020 12:19:28'	System	30 Nov 2020 17:19:32
	System	30 Nov 2020 17:19:32

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-07T11:19:15', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'df3d677e-ab2e-4eec-8790-ad594a0175f1' User entered 'No (N)'	System	07 Dec 2020 16:19:24
	System	07 Dec 2020 16:19:24

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-07T11:19:19', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'df3d677e-ab2e-4eec-8790-ad594a0175f1' User entered 'No (N)'	System	07 Dec 2020 16:19:24

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-07T11:19:22', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'df3d677e-ab2e-4eec-8790-ad594a0175f1' User entered '07 Dec 2020 11:19:22'	System	07 Dec 2020 16:19:24
	System	07 Dec 2020 16:19:24

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-14T11:15:52', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '8d098450-970b-40a3-99e7-84428262677e'	System	14 Dec 2020 16:21:08
User entered 'Yes (Y)'	System	14 Dec 2020 16:21:08

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-14T11:16:34', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '8d098450-970b-40a3-99e7-84428262677e' User entered 'No (N)'	System	14 Dec 2020 16:21:08
	System	14 Dec 2020 16:21:08

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you experienced any new COVID-19 disease symptoms 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-14T11:16:38', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '8d098450-970b-40a3-99e7-84428262677e' User entered 'No (N)'	System	14 Dec 2020 16:21:08
	System	14 Dec 2020 16:21:08

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Have you had to contact a healthcare provider 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-14T11:20:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '8d098450-970b-40a3-99e7-84428262677e'	System	14 Dec 2020 16:21:08
User entered 'Yes (Y)'	System	14 Dec 2020 16:21:08

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-14T11:20:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '8d098450-970b-40a3-99e7-84428262677e'	System	14 Dec 2020 16:21:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Dec 2020 16:21:08

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-14T11:20:58', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '8d098450-970b-40a3-99e7-84428262677e' User entered '14 Dec 2020 11:20:58'	System	14 Dec 2020 16:21:08
	System	14 Dec 2020 16:21:08

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-21T13:15:48', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ebc0e5a2-3369-42cd-83c3-1f1276354621' User entered 'Yes (Y)'	System	21 Dec 2020 18:16:07
	System	21 Dec 2020 18:16:07

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-21T13:15:53', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ebc0e5a2-3369-42cd-83c3-1f1276354621' User entered 'No (N)'	System	21 Dec 2020 18:16:07
	System	21 Dec 2020 18:16:07

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Have you experienced any new COVID-19 disease symptoms 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-21T13:15:57', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ebc0e5a2-3369-42cd-83c3-1f1276354621' User entered 'No (N)'	System	21 Dec 2020 18:16:07
	System	21 Dec 2020 18:16:07

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Have you had to contact a healthcare provider 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-21T13:16:02', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ebc0e5a2-3369-42cd-83c3-1f1276354621' User entered 'No (N)'	System	21 Dec 2020 18:16:07
	System	21 Dec 2020 18:16:07

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-21T13:16:04', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'ebc0e5a2-3369-42cd-83c3-1f1276354621' User entered '21 Dec 2020 13:16:04'	System	21 Dec 2020 18:16:07
	System	21 Dec 2020 18:16:07

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-28T13:05:11', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6c2967b9-cb9c-47fc-8287-cabbba847743' User entered 'No (N)'	System	28 Dec 2020 18:05:23
	System	28 Dec 2020 18:05:23

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-28T13:05:16', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6c2967b9-cb9c-47fc-8287-cabbba847743' User entered 'No (N)'	System	28 Dec 2020 18:05:23

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2020-12-28T13:05:18', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6c2967b9-cb9c-47fc-8287-cabbba847743' User entered '28 Dec 2020 13:05:18'	System	28 Dec 2020 18:05:23
	System	28 Dec 2020 18:05:23

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-04T06:42:25', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'eaf9cc61-ae9b-4ace-849d-b88f0e615b58'	System	04 Jan 2021 11:42:35
User entered 'No (N)'	System	04 Jan 2021 11:42:35

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-04T06:42:30', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'eaf9cc61-ae9b-4ace-849d-b88f0e615b58'	System	04 Jan 2021 11:42:35
User entered 'No (N)'	System	04 Jan 2021 11:42:35

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-04T06:42:33', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'eaf9cc61-ae9b-4ace-849d-b88f0e615b58' User entered '04 Jan 2021 06:42:33'	System	04 Jan 2021 11:42:35
	System	04 Jan 2021 11:42:35

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-11T11:32:54', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4b4e7505-a1fc-42a4-aa02-19e465331d1f' User entered 'No (N)'	System	11 Jan 2021 16:33:06
	System	11 Jan 2021 16:33:06

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-11T11:32:57', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4b4e7505-a1fc-42a4-aa02-19e465331d1f'	System	11 Jan 2021 16:33:06
User entered 'No (N)'	System	11 Jan 2021 16:33:06

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-11T11:32:59', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4b4e7505-a1fc-42a4-aa02-19e465331d1f' User entered '11 Jan 2021 11:32:59'	System	11 Jan 2021 16:33:06
	System	11 Jan 2021 16:33:06

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-18T06:42:43', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '63b39c71-1db4-4d7a-8f07-b2332d6d75f1'	System	18 Jan 2021 11:42:58
User entered 'No (N)'	System	18 Jan 2021 11:42:58

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-18T06:42:51', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '63b39c71-1db4-4d7a-8f07-b2332d6d75f1'	System	18 Jan 2021 11:42:58
User entered 'No (N)'	System	18 Jan 2021 11:42:58

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-18T06:42:54', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '63b39c71-1db4-4d7a-8f07-b2332d6d75f1' User entered '18 Jan 2021 06:42:54'	System	18 Jan 2021 11:42:58
	System	18 Jan 2021 11:42:58

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-25T07:43:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a6ce2d1a-8ae9-49f2-8561-022c1e7da52b'	System	25 Jan 2021 12:43:21
User entered 'No (N)'	System	25 Jan 2021 12:43:21

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-25T07:43:05', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a6ce2d1a-8ae9-49f2-8561-022c1e7da52b' User entered 'Yes (Y)'	System	25 Jan 2021 12:43:21
	System	25 Jan 2021 12:43:21

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-25T07:43:09', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a6ce2d1a-8ae9-49f2-8561-022c1e7da52b'	System	25 Jan 2021 12:43:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Jan 2021 12:43:21

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-01-25T07:43:12', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a6ce2d1a-8ae9-49f2-8561-022c1e7da52b' User entered '25 Jan 2021 07:43:12'	System	25 Jan 2021 12:43:21
	System	25 Jan 2021 12:43:21

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-01T10:26:38', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1967b381-d627-4050-9848-b02f3c61f8b7' User entered 'No (N)'	System	01 Feb 2021 23:07:39
	System	01 Feb 2021 23:07:39

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-01T10:26:44', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1967b381-d627-4050-9848-b02f3c61f8b7' User entered 'No (N)'	System	01 Feb 2021 23:07:39
	System	01 Feb 2021 23:07:39

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-01T10:26:46', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1967b381-d627-4050-9848-b02f3c61f8b7'	System	01 Feb 2021 23:07:39
User entered '01 Feb 2021 10:26:46'	System	01 Feb 2021 23:07:39

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-08T14:02:47', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '0b6dbae-7619-4c7a-8461-685bf7575f1f' User entered 'No (N)'	System	12 Feb 2021 13:49:19

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-08T14:02:52', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '0b6dbae-7619-4c7a-8461-685bf7575f1f' User entered 'No (N)'	System	12 Feb 2021 13:49:19

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-08T14:02:59', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '0b6dbae-7619-4c7a-8461-685bf7575f1f' User entered '08 Feb 2021 14:02:59'	System	12 Feb 2021 13:49:19

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-15T10:34:09', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '7aee39ae-bd0d-4082-8ae7-0464d5232dd2' User entered 'No (N)'	System	19 Feb 2021 17:51:14
	System	19 Feb 2021 17:51:14

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-15T10:34:12', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '7aee39ae-bd0d-4082-8ae7-0464d5232dd2' User entered 'No (N)'	System	19 Feb 2021 17:51:14

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-15T10:34:15', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '7aee39ae-bd0d-4082-8ae7-0464d5232dd2'	System	19 Feb 2021 17:51:14
User entered '15 Feb 2021 10:34:15'	System	19 Feb 2021 17:51:14

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-22T07:10:47', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'de8b967a-55ea-42b3-93b7-e3ed660bc6c0' User entered 'No (N)'	System	22 Feb 2021 12:11:01
	System	22 Feb 2021 12:11:01

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-22T07:10:52', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'de8b967a-55ea-42b3-93b7-e3ed660bc6c0' User entered 'No (N)'	System	22 Feb 2021 12:11:01
	System	22 Feb 2021 12:11:01

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-02-22T07:10:54', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'de8b967a-55ea-42b3-93b7-e3ed660bc6c0' User entered '22 Feb 2021 07:10:54'	System	22 Feb 2021 12:11:01
	System	22 Feb 2021 12:11:01

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-01T11:05:22-05:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4d130aca-c9e0-45cb-a04b-7f8a8739b8d6'	System	01 Mar 2021 16:05:32
User entered 'No (N)'	System	01 Mar 2021 16:05:32

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-01T11:05:24-05:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4d130aca-c9e0-45cb-a04b-7f8a8739b8d6'	System	01 Mar 2021 16:05:32
User entered 'No (N)'	System	01 Mar 2021 16:05:32

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-01T11:05:26-05:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '4d130aca-c9e0-45cb-a04b-7f8a8739b8d6'	System	01 Mar 2021 16:05:32
User entered '01 Mar 2021 11:05:26'	System	01 Mar 2021 16:05:32

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-08T09:28:15-05:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'fd36c7ce-ab5f-45cb-a23b-ebb314667802'	System	08 Mar 2021 14:28:32
User entered 'No (N)'	System	08 Mar 2021 14:28:32

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-08T09:28:25-05:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'fd36c7ce-ab5f-45cb-a23b-ebb314667802'	System	08 Mar 2021 14:28:32
User entered 'No (N)'	System	08 Mar 2021 14:28:32

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-08T09:28:28-05:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'fd36c7ce-ab5f-45cb-a23b-ebb314667802'	System	08 Mar 2021 14:28:32
User entered '08 Mar 2021 09:28:28'	System	08 Mar 2021 14:28:32

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-15T06:15:37-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1518cb79-887d-4be8-9c48-101759ae2ad8'	System	22 Mar 2021 13:57:26
User entered 'No (N)'	System	22 Mar 2021 13:57:26

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-15T06:15:42-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1518cb79-887d-4be8-9c48-101759ae2ad8'	System	22 Mar 2021 13:57:26
User entered 'No (N)'	System	22 Mar 2021 13:57:26

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-15T06:15:44-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '1518cb79-887d-4be8-9c48-101759ae2ad8' User entered '15 Mar 2021 06:15:44'	System	22 Mar 2021 13:57:26

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-22T09:57:22-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6ffbf904-b311-4e89-8ee6-997cccce8539'	System	22 Mar 2021 13:57:30
User entered 'No (N)'	System	22 Mar 2021 13:57:30

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-22T09:57:25-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6ffbf904-b311-4e89-8ee6-997cccce8539'	System	22 Mar 2021 13:57:30
User entered 'No (N)'	System	22 Mar 2021 13:57:30

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-22T09:57:27-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '6ffbf904-b311-4e89-8ee6-997cccce8539'	System	22 Mar 2021 13:57:30
User entered '22 Mar 2021 09:57:27'	System	22 Mar 2021 13:57:30

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-29T07:42:26-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2c1eb38a-6d75-4c0d-93e4-a473e518142f' User entered 'No (N)'	System	29 Mar 2021 11:42:35
	System	29 Mar 2021 11:42:35

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-29T07:42:29-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2c1eb38a-6d75-4c0d-93e4-a473e518142f' User entered 'No (N)'	System	29 Mar 2021 11:42:35

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-29T07:42:31-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '2c1eb38a-6d75-4c0d-93e4-a473e518142f' User entered '29 Mar 2021 07:42:31'	System	29 Mar 2021 11:42:35
	System	29 Mar 2021 11:42:35

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-05T07:23:24-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a9a7d6a2-4a23-40dd-8d59-be0eede18813' User entered 'No (N)'	System	05 Apr 2021 11:23:36
	System	05 Apr 2021 11:23:36

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-05T07:23:31-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a9a7d6a2-4a23-40dd-8d59-be0eede18813' User entered 'No (N)'	System	05 Apr 2021 11:23:36
	System	05 Apr 2021 11:23:36

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-05T07:23:34-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a9a7d6a2-4a23-40dd-8d59-be0eede18813' User entered '05 Apr 2021 07:23:34'	System	05 Apr 2021 11:23:36
	System	05 Apr 2021 11:23:36

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-12T06:19:20-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bd00fbe9-9c01-456b-b81d-a190a6322713'	System	16 Apr 2021 13:12:47
User entered 'No (N)'	System	16 Apr 2021 13:12:47

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-12T06:19:26-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bd00fbe9-9c01-456b-b81d-a190a6322713'	System	16 Apr 2021 13:12:47
User entered 'No (N)'	System	16 Apr 2021 13:12:47

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-12T06:19:28-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'bd00fbe9-9c01-456b-b81d-a190a6322713'	System	16 Apr 2021 13:12:47
User entered '12 Apr 2021 06:19:28'	System	16 Apr 2021 13:12:47

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-19T05:55:15-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9eb12ce1-0d46-4a58-b908-c1bfed0f0061'	System	22 Apr 2021 14:27:00
User entered 'Yes (Y)'	System	22 Apr 2021 14:27:00

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-19T05:55:19-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9eb12ce1-0d46-4a58-b908-c1bfed0f0061' User entered 'No (N)'	System	22 Apr 2021 14:27:00
	System	22 Apr 2021 14:27:00

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Have you experienced any new COVID-19 disease symptoms 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-19T05:55:22-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9eb12ce1-0d46-4a58-b908-c1bfed0f0061' User entered 'No (N)'	System	22 Apr 2021 14:27:00
	System	22 Apr 2021 14:27:00

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Have you had to contact a healthcare provider 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-19T05:55:28-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9eb12ce1-0d46-4a58-b908-c1bfed0f0061'	System	22 Apr 2021 14:27:00
User entered 'Yes (Y)'	System	22 Apr 2021 14:27:00

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-19T05:55:31-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9eb12ce1-0d46-4a58-b908-c1bfed0f0061'	System	22 Apr 2021 14:27:00
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Apr 2021 14:27:00

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-19T05:55:33-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '9eb12ce1-0d46-4a58-b908-c1bfed0f0061' User entered '19 Apr 2021 05:55:33'	System	22 Apr 2021 14:27:00
	System	22 Apr 2021 14:27:00

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-26T21:57:05-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b227dbc2-8ddb-425f-83e2-baae5a0c6e4f'	System	03 May 2021 10:26:30
User entered 'No (N)'	System	03 May 2021 10:26:30

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-26T21:57:07-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b227dbc2-8ddb-425f-83e2-baae5a0c6e4f'	System	03 May 2021 10:26:30
User entered 'No (N)'	System	03 May 2021 10:26:30

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-04-26T21:57:09-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'b227dbc2-8ddb-425f-83e2-baae5a0c6e4f'	System	03 May 2021 10:26:30
User entered '26 Apr 2021 21:57:09'	System	03 May 2021 10:26:30

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-05-03T06:26:27-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a211d52e-ec37-4169-b83a-41342bdf7c29'	System	03 May 2021 10:26:38
User entered 'No (N)'	System	03 May 2021 10:26:38

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

Have you been exposed to someone with 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 (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-05-03T06:26:29-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a211d52e-ec37-4169-b83a-41342bdf7c29'	System	03 May 2021 10:26:38
User entered 'No (N)'	System	03 May 2021 10:26:38

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-05-03T06:26:31-04:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: 'a211d52e-ec37-4169-b83a-41342bdf7c29'	System	03 May 2021 10:26:38
User entered '03 May 2021 06:26:31'	System	03 May 2021 10:26:38

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '14 Nov 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '18 Nov 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '21 Nov 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '25 Nov 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '28 Nov 2022 00:01'	System	20 Nov 2020 10:20:44

US3742463

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:22:22

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:20:44
Amendment Manager: User entered '02 Dec 2022 23:59'	System	20 Nov 2020 10:20:44

US3742463

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:22:22

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-01T11:05:16-05:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '758d3757-8f1f-49b7-9229-3bc96b951ad3'	System	01 Mar 2021 16:05:22
User entered 'No (N)'	System	01 Mar 2021 16:05:22

US3742463

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:22:22

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:19:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (256BC1F5-1459-45C6-9C95-8B1F4A955950)', Time: '2021-03-01T11:05:18-05:00', User OID: 'PatientReportedOutcome (US3742463)', ODM File OID: '758d3757-8f1f-49b7-9229-3bc96b951ad3'	System	01 Mar 2021 16:05:22
User entered '01 Mar 2021 11:05:18'	System	01 Mar 2021 16:05:22

US3742463

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Dec 2020 15:37:05

US3742463

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '22 Dec 2020'	Sherry McCammon (b) (4)	22 Dec 2020 15:37:05

US3742463

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	22 Dec 2020 15:37:05

US3742463

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:37:05

US3742463

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Dec 2020 15:37:11

US3742463

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:36:26
User entered 'I'	System	22 Dec 2020 15:37:11

US3742463

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:03:35

US3742463

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:03:35

US3742463

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:03:35

US3742463

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4)	26 Jan 2021 15:03:35
	(b) (4), (b) (6)	

US3742463

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:03:43

US3742463

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User entered 'I'	System	26 Jan 2021 15:03:43

US3742463

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Feb 2021 15:19:10

US3742463

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User entered '24 Feb 2021'	Sherry McCammon (b) (4)	25 Feb 2021 15:19:10

US3742463

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	25 Feb 2021 15:19:10

US3742463

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User entered empty.	Sherry McCammon (b) (4)	25 Feb 2021 15:19:10

US3742463

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	25 Feb 2021 15:19:21

US3742463

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User entered 'I'	System	25 Feb 2021 15:19:21

US3742463

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:01

US3742463

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:01

US3742463

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:01

US3742463

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:22:22

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User entered 'Per participant pap smear will not be evaluated for 1 year. No treatment required no additional evaluation required.'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:01

US3742463

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 16:17:10

US3742463

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:55:18
User entered 'I'	System	24 Mar 2021 16:17:10

US3742463

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Apr 2021 14:11:30
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered '17 Apr 2021'	Sherry McCammon (b) (4)	19 Apr 2021 14:11:30
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry McCammon (b) (4)	19 Apr 2021 14:11:30
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	19 Apr 2021 14:11:30

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	19 Apr 2021 14:11:36
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Apr 2021 14:11:36
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Apr 2021 14:11:36
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:11:36

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Apr 2021 14:11:36
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Apr 2021 14:11:36
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Apr 2021 14:11:36
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Apr 2021 14:11:36
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:11:36

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Apr 2021 14:11:36
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:11:36

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Apr 2021 14:11:36
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:11:36

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Apr 2021 14:11:36
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:22:22

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 14:11:36

US3742463

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:22

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	19 Apr 2021 14:11:41
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:22:22

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	19 Apr 2021 14:11:41
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Apr 2021 14:11:56
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered '17 Apr 2021'	Sherry McCammon (b) (4)	19 Apr 2021 14:11:56
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered '08:30'	Sherry McCammon (b) (4)	19 Apr 2021 14:11:56
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
User entered '17 Apr 2021 08:30'	System	19 Apr 2021 14:11:56

US3742463

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	19 Apr 2021 14:21:24
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	19 Apr 2021 14:12:03
	(b) (4)	

US3742463

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:22:22

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 14:12:03

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:58:54

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:58:54

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:58:54

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:22:22

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 14:58:54

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:52:46
Signature has been broken.	Kaitlin Mason (b) (4)	12 Apr 2021 15:52:26
User entered '25 Jan 2021' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	12 Apr 2021 15:52:26
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '6 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 15:01:30

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:52:46
User entered '0'	Kaitlin Mason (b) (4)	12 Apr 2021 15:52:26
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:52:43

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:01:30

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:52:46
User entered 'Amendment 6 or later (Amendment 6 or later)'	Kaitlin Mason (b) (4)	12 Apr 2021 15:52:26
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:52:43

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:01:30

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:01:30

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:01:30

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:01:30

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:01:30

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered empty.	System	26 Jan 2021 15:01:30

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:22:22

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered empty.	System	26 Jan 2021 15:01:30

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:59:25

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:59:25

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '07:39'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:59:25

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered '25 Jan 2021 07:39'	System	26 Jan 2021 14:59:25

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:22:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:59:40

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:22:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '25 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:59:40

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:22:22

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '07:42'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:59:40

US3742463

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:21:53
User entered '25 Jan 2021 07:42'	System	26 Jan 2021 14:59:40

US3742463

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:22:22

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:54:15

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:11
Data point term sent to Coder	System	21 Dec 2020 13:56:58
User entered 'Urinary tract infection'	(b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 19:44:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:44:36
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 19:44:36
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:56:00
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 19:44:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:44:36
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 19:44:36
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:56:00
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 13:56:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 13:56:57
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 13:56:57
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:56:00
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '28 Nov 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User entered empty.	System	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User entered empty.	System	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 19:44:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:44:36
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 19:44:36
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:56:00
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 19:44:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:44:36
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 19:44:36
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:56:00
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 19:44:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:44:36
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 19:44:36
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:56:00
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:57:40
Signature has been broken.	(b) (4)	
	Sherry McCammon (b) (4)	23 Mar 2021 19:03:51
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:16:21
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.	(b) (4)	
' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	22 Feb 2021 14:25:18
User entered '0' reason for change: New Information	(b) (4)	
	(b) (4)	22 Feb 2021 14:25:13
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.	(b) (4), (b) (6)	05 Feb 2021 12:49:31
' (Site from DM).		
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Dec 2020 19:44:36
User entered '1' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 19:44:36
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Dec 2020 13:56:00
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '1' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 14:25:13
User entered '0'	Kaitlin Mason (b) (4)	21 Dec 2020 13:56:00
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User entered '0'	System	21 Dec 2020 13:56:00

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User entered '1'	System	21 Dec 2020 19:44:36

US3742463

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:22:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User coded data point as SOC: Infections and infestations, HLGT: Protozoal infectious disorders, HLT: Trichomonas infections, PT: Vulvovaginitis trichomonal, LLT: Trichomonal vaginitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:16
Data point term sent to Coder	System	21 Dec 2020 13:58:58
User entered 'trichomoniasis vaginalis'	(b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 19:45:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:45:46
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 19:45:46
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:58:53
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:45:46
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 19:45:46
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:58:53
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User entered empty.	System	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:57:40
Signature has been broken.	Sherry McCammon (b) (4)	23 Mar 2021 18:59:58
User entered 'No (N)' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Mar 2021 18:59:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:57:40
Signature has been broken.	Sherry McCammon (b) (4)	23 Mar 2021 18:59:58
User entered '18 Jan 2021' reason for change: Data Entry Error	Sherry McCammon (b) (4)	23 Mar 2021 18:59:58
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User entered empty.	System	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 19:45:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:45:46
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 19:45:46
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:58:53
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:58:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 19:45:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:45:46
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 19:45:46
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:58:53
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:58:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Dec 2020 19:45:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Dec 2020 19:45:46
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 19:45:46
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Dec 2020 13:58:53
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #7 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:16:49
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #7 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4)	22 Feb 2021 14:25:40
User entered '0' reason for change: New Information	Kaitlin Mason (b) (4)	22 Feb 2021 14:25:35
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #7 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 12:49:43
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Dec 2020 19:45:46
User entered '1' reason for change: New Information	(b) (4), (b) (6)	21 Dec 2020 19:45:46
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Dec 2020 13:58:53
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 13:58:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '1' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 14:25:35
User entered '0'	Kaitlin Mason (b) (4)	21 Dec 2020 13:58:53
	(b) (4)	
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:57:40
Signature has been broken.	Sherry McCammon (b) (4)	23 Mar 2021 18:59:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Sherry McCammon (b) (4)	23 Mar 2021 18:59:58
Data Entry Error	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	21 Dec 2020 13:58:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User entered '0'	System	21 Dec 2020 13:58:53

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43
User entered 'I'	System	21 Dec 2020 19:45:46

US3742463

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:22:22

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if there is an associated medical condition related to this abnormal lab result. If so, please update term. Else, confirm there is no related condition.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:27:42
Query 'Per DM CLR: Please review if there is an associated medical condition related to this abnormal lab result. If so, please update term. Else, confirm there is no related condition.' answered with 'No related condition' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 17:18:24
User opened query 'Per DM CLR: Please review if there is an associated medical condition related to this abnormal lab result. If so, please update term. Else, confirm there is no related condition.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:26:10
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:26:03
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Smear cervix abnormal, LLT: Pap smear abnormal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 16:09:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 16:09:47
Data point term sent to Coder	System	22 Dec 2020 15:36:21
User entered 'ABNORMAL PAP RESULT'	Sherry McCammon (b) (4) (b) (4)	22 Dec 2020 15:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 15:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 15:44:34
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	29 Dec 2020 15:44:34
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 15:36:10
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered '14 Dec 2020'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 15:36:10

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 15:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 15:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 15:44:34
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	29 Dec 2020 15:44:34
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 15:36:10
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

Death

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 15:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 15:44:34
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	29 Dec 2020 15:44:34
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 15:36:10
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Dec 2020 15:44:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 15:44:34
User entered 'Not Related (NOT RELATED)' reason for change: New Information	(b) (4), (b) (6)	29 Dec 2020 15:44:34
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 15:36:10
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

None

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
	(b) (4)	
Signature has been broken.	Kaitlin Mason (b) (4)	05 Apr 2021 17:19:02
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	05 Apr 2021 17:19:02
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
User closed query 'Per DM CLR-RQ: Response noted. However, there is no CM with this verbatim indication recorded in the con med page. Either update CM indication and/or update AE indication OR provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 13:49:38
Query 'Per DM CLR-RQ: Response noted. However, there is no CM with this verbatim indication recorded in the con med page. Either update CM indication and/or update AE indication OR provide clarification. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 17:19:23
Signature has been broken.	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 17:19:02
User entered '0' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 17:19:02
User opened query 'Per DM CLR-RQ: Response noted. However, there is no CM with this verbatim indication recorded in the con med page. Either update CM indication and/or update AE indication OR provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:28:17
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 15:26:43
User signature succeeded.	Karen Kotloff (b) (4) (b) (4)	23 Feb 2021 18:26:03
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	22 Feb 2021 14:27:05

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM). User entered '1'	(b) (4), (b) (6) (b) (4)	05 Feb 2021 12:49:54
	Sherry McCammon (b) (4) (b) (4)	22 Dec 2020 15:36:10

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 14:26:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Feb 2021 14:26:59
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	22 Feb 2021 14:26:59
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 15:36:10
User entered empty.	Sherry McCammon (b) (4) (b) (4)	22 Dec 2020 15:36:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Dec 2020 15:36:10
	(b) (4)	

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Dec 2020 15:44:34

US3742463

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:22:22

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	29 Dec 2020 15:44:34

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:22:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:56:40
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is NO on the eDiary, however, this patient's Concomitant Procedures, Concomitant Medications, or Medical History indicate that they have received a cosmetic injection. Please review and confirm if the eDiary response is in error	(b) (4), (b) (6)	01 Apr 2021 12:23:15
' (Site from DM). Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is NO on the eDiary, however, this patient's Concomitant Procedures, Concomitant Medications, or Medical History indicate that they have received a cosmetic injection. Please review and confirm if the eDiary response is in error	(b) (4), (b) (6)	29 Mar 2021 13:23:01
' answered with 'This is not a cosmetic injection this is for medical injection for hyperhidrosis. ' (Site from DM). User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is NO on the eDiary, however, this patient's Concomitant Procedures, Concomitant Medications, or Medical History indicate that they have received a cosmetic injection. Please review and confirm if the eDiary response is in error	(b) (4), (b) (6)	23 Mar 2021 15:42:07
' (Site from DM). User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Per CDM : In Diary Dose 2(1) - Temperature Day 2, Tylenol was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 12:32:46

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:22:22

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Query 'Per CDM : In Diary Dose 2(1) - Temperature Day 2, Tylenol was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' answered with 'Meds are listed in ConMed' (Site from DM).	Sherry McCammon (b) (4)	05 Nov 2020 16:34:16
User opened query 'Per CDM : In Diary Dose 2(1) - Temperature Day 2, Tylenol was taken by the subject to TREAT/PREVENT pain or fever, however, no corresponding ConMed is recorded. Please review and reconcile' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 06:04:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 14:03:40

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: ANTIHIDROTICS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Sep 2020 14:45:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:45:41
Data point term sent to Coder	System	28 Sep 2020 14:05:44
User entered 'BOTOX'	(b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'HYPERHIDROSIS'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
	(b) (4)	
Signature has been broken.	Sherry McCammon (b) (4)	25 Feb 2021 20:39:59
	(b) (4)	
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User entered '100'	(b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Per CDM: Please note that IU = International Units is an available option in the Dose units field. Kindly determine if this is a more appropriate option. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 10:30:10
Query 'Per CDM: Please note that IU = International Units is an available option in the Dose units field. Kindly determine if this is a more appropriate option. Please review and reconcile. ' answered with 'IU IS NOT AN APPROPRIATE OPTION IN THIS SITUATION. "UNITS" IS AN ACCURATE DOSE ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	02 Oct 2020 14:24:31
User opened query 'Per CDM: Please note that IU = International Units is an available option in the Dose units field. Kindly determine if this is a more appropriate option. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:40:21
User entered 'UNITS'	(b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '11 Jun 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 14:06:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 14:06:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 14:06:10
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 14:04:44
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 14:04:44

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Jan 2021 21:38:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 21:38:53
Data point term sent to Coder	System	25 Jan 2021 21:38:00
Coding entries removed.	Kaitlin Mason (b) (4) (b) (4)	25 Jan 2021 21:37:00
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 14:08:17
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 Sep 2020 14:08:17
Data point term sent to Coder	System	28 Sep 2020 14:06:46
User entered 'NEXPLANON'	(b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:27:12
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	25 Jan 2021 21:35:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	25 Jan 2021 21:35:54
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 23:27:30
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'CONTRACEPTION'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Per DM CLR: Please review the dosage as this is not the expected single dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:38:54
Query 'Per DM CLR: Please review the dosage as this is not the expected single dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 20:38:56
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 20:38:37
User opened query 'Per DM CLR: Please review the dosage as this is not the expected single dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:54:23
User entered '63'	(b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 20:38:37
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Inplant' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:38:37
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Per DM CLR: Please verify the FREQUENCY of the dosage as 'Once' since the start and stop date duration is more than 1 day. Please update FREQUENCY or dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:38:59
Query 'Per DM CLR: Please verify the FREQUENCY of the dosage as 'Once' since the start and stop date duration is more than 1 day. Please update FREQUENCY or dates as appropriate.'	(b) (4), (b) (6)	05 Nov 2020 20:39:10
answered with 'updated' (Site from DM).		
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 20:37:32
User opened query 'Per DM CLR: Please verify the FREQUENCY of the dosage as 'Once' since the start and stop date duration is more than 1 day. Please update FREQUENCY or dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:54:07
User entered 'once (ONCE)'	(b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Continuous for 3 years' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:37:32
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 14:51:41
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 21:37:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 21:37:11
User entered 'Other (OTHER)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	25 Jan 2021 21:37:11
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 21:37:00
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	25 Jan 2021 21:37:00
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'route is appropriate ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	25 Jan 2021 21:36:30
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 23:27:50
User entered 'Transdermal (TRANSDERMAL)'	(b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'subdermal' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 21:37:00
User entered empty.	Kaitlin Mason (b) (4)	28 Sep 2020 14:06:02
	(b) (4)	
	(b) (4), (b) (6)	

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '10 Jul 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:42:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '16 Nov 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	17 Nov 2020 14:42:24
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User entered empty.	System	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User entered empty.	System	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:25
User entered empty.	System	28 Sep 2020 14:06:02

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 14:16:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	28 Jan 2021 14:16:18
Data point term sent to Coder Coding entries removed.	System	28 Jan 2021 14:15:23
	(b) (4), (b) (6)	28 Jan 2021 14:15:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 14:15:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	04 Nov 2020 14:15:23
Data point term sent to Coder User entered 'ibuprofen'	System	04 Nov 2020 14:15:02
	Hassan Haji (b) (4)	04 Nov 2020 14:14:43
	(b) (4)	

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
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 GENERALIZED PAIN AND FEVER 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 GENERALIZED PAIN AND FEVER did not meet the AE reporting criteria. '(Site from DM).	(b) (4), (b) (6)	24 Mar 2021 18:57:54
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the GENERALIZED PAIN AND FEVER 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 GENERALIZED PAIN AND FEVER did not meet the AE reporting criteria. ' answered with 'did not meet ae reporting criteria ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	17 Mar 2021 19:56:00

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Indication](#)

Audit	User	Time (GMT)
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 GENERALIZED PAIN AND FEVER 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 GENERALIZED PAIN AND FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 02:51:25
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Per DM CLR: Please update the indication to reflect the type/location of the PAIN (eg, pain at injection site). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 07:59:08
Query 'Per DM CLR: Please update the indication to reflect the type/location of the PAIN (eg, pain at injection site). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' answered with 'UPDATED TO INCLUDE GENERALIZED ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:15:50
User entered 'GENERALIZED PAIN AND FEVER' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Jan 2021 14:15:10
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:27:48

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' answered with 'does not meet ae reporting criteria ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	25 Jan 2021 21:37:42
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 23:28:31
User opened query 'Per DM CLR: Please update the indication to reflect the type/location of the PAIN (eg, pain at injection site). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 23:28:22
User entered 'pain and fever'	Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '200'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'once (ONCE)'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) Hassan Haji (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '27 Oct 2020'	(b) (4) Hassan Haji (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 14:15:08
User entered 'Yes (Y)'	Hassan Haji (b) (4)	04 Nov 2020 14:14:43
	(b) (4)	

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	(b) (4)	04 Nov 2020 14:15:08
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	04 Nov 2020 14:14:43
User entered '27 Oct 2020'	Hassan Haji (b) (4)	04 Nov 2020 14:14:43
	(b) (4)	

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User entered empty.	System	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User entered empty.	System	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:29
User entered empty.	System	04 Nov 2020 14:14:43

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
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)	28 Jan 2021 14:18:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Jan 2021 14:18:18
Data point term sent to Coder	System	28 Jan 2021 14:17:25
Coding entries removed.	(b) (4), (b) (6)	28 Jan 2021 14:16:49
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)	04 Nov 2020 14:34:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 14:34:23
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)	04 Nov 2020 14:19:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 14:19:23
Data point term sent to Coder	System	04 Nov 2020 14:18:09
User entered 'Tylenol'	Hassan Haji (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
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 GENERALIZED PAIN AND FEVER 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 GENERALIZED PAIN AND FEVER did not meet the AE reporting criteria. '(Site from DM).	(b) (4), (b) (6)	08 Apr 2021 03:43:32
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the GENERALIZED PAIN AND FEVER 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 GENERALIZED PAIN AND FEVER did not meet the AE reporting criteria. ' answered with 'did not meet ae reporting criteria - taken for reactogenicity' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	05 Apr 2021 17:20:40

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Indication](#)

Audit	User	Time (GMT)
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 GENERALIZED PAIN AND FEVER 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 GENERALIZED PAIN AND FEVER did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 02:51:48
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Per DM CLR: Please update the indication to reflect the type/location of the PAIN (eg, pain at injection site). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 07:59:26
Query 'Per DM CLR: Please update the indication to reflect the type/location of the PAIN (eg, pain at injection site). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' answered with 'UPDATED TO INCLUDE GENERALIZED' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 14:17:56
User entered 'GENERALIZED PAIN AND FEVER' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Jan 2021 14:16:49
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:27:55

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' answered with 'does not meet ae reporting criteria ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	25 Jan 2021 21:38:01
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the FEVER 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 of 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 FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 23:29:05
User opened query 'Per DM CLR: Please update the indication to reflect the type/location of the PAIN (eg, pain at injection site). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 23:28:55
User entered 'pain and fever'	Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '1000'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'mg (mg)'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'once (ONCE)'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) Hassan Haji (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Oral (ORAL)'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) Hassan Haji (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '28 Oct 2020'	(b) (4) Hassan Haji (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '28 Oct 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) Hassan Haji (b) (4) (b) (4)	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User entered empty.	System	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User entered empty.	System	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:32
User entered empty.	System	04 Nov 2020 14:17:47

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:10
Data point term sent to Coder	System	21 Dec 2020 13:48:47
User entered 'Influenza Vaccine'	(b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Influenza Prophylaxis'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0.5'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User entered empty.	System	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User entered empty.	System	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:42
User entered empty.	System	21 Dec 2020 13:47:50

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:10
Data point term sent to Coder	System	21 Dec 2020 13:50:50
User entered 'Ciprofloxacin'	(b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Per DM CLR : Please review "Other Action Taken" field in AE eCRF as it does not reflect this Con Med for AE #1. Please reconcile and correct response as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 13:50:40
Query 'Per DM CLR : Please review "Other Action Taken" field in AE eCRF as it does not reflect this Con Med for AE #1. Please reconcile and correct response as appropriate. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	22 Feb 2021 14:24:27
User opened query 'Per DM CLR : Please review "Other Action Taken" field in AE eCRF as it does not reflect this Con Med for AE #1. Please reconcile and correct response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:46:26
User entered 'Urinary tract infection'	(b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '500'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User entered '2'	System	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User entered '1'	System	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:43
User entered '804 (804)'	System	21 Dec 2020 13:50:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:33:15
Data point term sent to Coder	System	21 Dec 2020 13:53:51
User entered 'metronidazole'	(b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Per DM CLR : Please review "Other Action Taken" field in AE eCRF as it does not reflect this Con Med for AE #2. Please reconcile and correct response as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 13:50:53
Query 'Per DM CLR : Please review "Other Action Taken" field in AE eCRF as it does not reflect this Con Med for AE #2. Please reconcile and correct response as appropriate. ' answered with 'updated' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	22 Feb 2021 14:24:34
User opened query 'Per DM CLR : Please review "Other Action Taken" field in AE eCRF as it does not reflect this Con Med for AE #2. Please reconcile and correct response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 06:47:31
User entered 'trichomoniasis vaginalis'	(b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '500'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 15:38:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	22 Dec 2020 15:38:30
User entered '18 Dec 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4)	22 Dec 2020 15:38:30
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	22 Dec 2020 15:38:21
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 18:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User entered '2'	System	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User entered '1'	System	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:22:22

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 21:21:47
User entered '804 (804)'	System	21 Dec 2020 13:53:36

US3742463

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:22:22

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:53:57
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	25 Feb 2021 15:20:04
	(b) (4)	