

US3392287 (Prod: Benchmark Research - Metairie - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:22:36

All time stamps listed in this document are displayed in GMT

US3392287

Form: Participant Creation

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Participant ID

US3392287

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

US3392287

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
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	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Date of Informed Consent (<i>dd MMM yyyy</i>)	16 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

US3392287

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN JAN 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN JAN 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Condition	OBESITY
Start date (dd MMM yyyy)	UN JAN 1982
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 1982
Start Year (derived)	1982
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN JAN 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	16 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:16 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:16
Height (<i>xxx.x</i>)	62 in
Weight (<i>xxx.x</i>)	250.0 lb
BMI (<i>xxx.x</i>)	45.82121 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	61 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 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) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

Date of assessment (dd MMM yyyy) 16 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) UN JAN 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 03:22:33

Generated On: 09 Jun 2021 17:22:36

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) 20 Feb 2021 03:22:33

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:01:17

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 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) 20 Feb 2021 03:01:17

Generated On: 09 Jun 2021 17:22:36

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

What was the participant's randomization number? 190882

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) 20 Feb 2021 03:01:17

Generated On: 09 Jun 2021 17:22:36

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 03:01:17

Generated On: 09 Jun 2021 17:22:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 11:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 03:01:17

Generated On: 09 Jun 2021 17:22:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 12:50
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:01:17

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 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: Exposure

Data signed: (b) (4) 20 Feb 2021 03:01:16

Generated On: 09 Jun 2021 17:22:36

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:04 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 12:04

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) 20 Feb 2021 03:01:17

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 SEP 2020
Collection time (00:00-23:59)	11:45 (24 HR)
Collection date and time (derived)	16 SEP 2020 11:45

US3392287

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 03:01:16

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:40	16 SEP 2020 11:40
Nasopharyngeal Swab 2	No		

US3392287

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:01:16

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 12:48

PC Open Date & Time

16 SEP 2020 12:24

PC Close Date & Time

16 SEP 2020 14:54

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 96.0 °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	16 SEP 2020 22:56
PC Open Date & Time	16 SEP 2020 15:49
PC Close Date & Time	17 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 16:17

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 23:11

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

97.7 °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

19 SEP 2020 19:48

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

20 SEP 2020 19:19

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 21:51

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 23:40

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

16 SEP 2020 12:45

PC Open Date & Time

16 SEP 2020 12:24

PC Close Date & Time

16 SEP 2020 14:54

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

16 SEP 2020 22:53

PC Open Date & Time

16 SEP 2020 15:49

PC Close Date & Time

17 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

17 SEP 2020 16:15

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 12:02

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 19:40

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 19:16

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 21:51

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 23:37

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 12:46
PC Open Date & Time	16 SEP 2020 12:24
PC Close Date & Time	16 SEP 2020 14:54

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 22:54
PC Open Date & Time	16 SEP 2020 15:49
PC Close Date & Time	17 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 ☒

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

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)

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US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:04
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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)

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 19:41
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

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EAB) (1725)

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 19:17
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

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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US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 21:52
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

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EAB) (1725)

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 23:38
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 24 SEP 2020 02:57

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 24 SEP 2020 02:58

PC Open Date & Time 23 SEP 2020 12:00

PC Close Date & Time 24 SEP 2020 11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 SEP 2020 02:58
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3392287

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:14:31

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392287

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:14:31

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:40:44

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392287

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:40:44

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:21:20

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392287

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:21:20

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 10:15
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	11:06 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:06
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3392287

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

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.

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

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) 12 OCT 2020

What was the treatment time? (00:00-23:59) 10:33 (24 HR)

Treatment Date and Time (derived) 12 OCT 2020 10:33

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

US3392287

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

10:20 (24 HR)

Collection date and time (derived)

12 OCT 2020 10:20

US3392287

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 04:49:58

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)			12 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:16	12 OCT 2020 10:16
Nasopharyngeal Swab 2	No		

US3392287

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 04:49:58

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 11:01

PC Open Date & Time

12 OCT 2020 10:53

PC Close Date & Time

12 OCT 2020 13:23

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °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):

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

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

PC Time Stamp 12 OCT 2020 20:17

PC Open Date & Time 12 OCT 2020 14:18

PC Close Date & Time 13 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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	13 OCT 2020 22:12
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

97.2 °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

14 OCT 2020 17:31

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

97.7 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

16 OCT 2020 01:19

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

16 OCT 2020 23:47

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

96.6 °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):

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

False

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

17 OCT 2020 23:05

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

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

18 OCT 2020 23:56

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 11:01

PC Open Date & Time

12 OCT 2020 10:53

PC Close Date & Time

12 OCT 2020 13:23

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 OCT 2020 20:18

PC Open Date & Time

12 OCT 2020 14:18

PC Close Date & Time

13 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 22:10

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 17:29

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

16 OCT 2020 01:20

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 23:45

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 23:03

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 23:55

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

No ☒

Yes ☐

PC Time stamp	12 OCT 2020 11:02
PC Open Date & Time	12 OCT 2020 10:53
PC Close Date & Time	12 OCT 2020 13:23

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

No ☒

Yes ☐

PC Time stamp	12 OCT 2020 20:19
PC Open Date & Time	12 OCT 2020 14:18
PC Close Date & Time	13 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 ☒

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 22:10
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 ☒

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 17:29
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 ☒

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 01:20
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

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)

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 23:44
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 ☒

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 23:02
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 ☒

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 23:56
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3392287

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:04:57

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:04:57

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:48:33

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392287

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:48:33

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:31:35

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392287

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:31:35

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 05:30:19

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 05:30:19

Generated On: 09 Jun 2021 17:22:36

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) _____

US3392287

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 05:30:19

Generated On: 09 Jun 2021 17:22:36

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.

US3392287

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 05:30:19

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 NOV 2020

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

06 NOV 2020 10:30

US3392287

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 05:30:19

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 01:21:19

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	23 NOV 2020 00:19:42
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	27 NOV 2020 00:01:36
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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	04 DEC 2020 00:18:17
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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 DEC 2020 00:01:43
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	18 DEC 2020 23:49:19
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

25 DEC 2020 11:33:49

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	03 JAN 2021 12:10:36
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 00:07:11

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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	17 JAN 2021 13:30:41
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 00:47:50

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

29 JAN 2021 00:49:09

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	09 FEB 2021 12:10:52
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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	14 FEB 2021 12:01:06
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 12:01:23

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

26 FEB 2021 08:03:23

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

05 MAR 2021 09:01:27

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 MAR 2021 09:02:18
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

22 MAR 2021 01:50:53

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 02:08:49

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 00:13:59

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 17:59:25

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

20 APR 2021 11:11:28

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

26 APR 2021 18:15:45

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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 APR 2021 00:10:37
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 243

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

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

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

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

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

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

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 292

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Patient Cloud Open Date & Time	20 AUG 2021 00:01
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Patient Cloud Close Date & Time	24 AUG 2021 23:59
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US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Patient Cloud Open Date & Time	27 AUG 2021 00:01
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Patient Cloud Close Date & Time	31 AUG 2021 23:59
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US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Patient Cloud Open Date & Time	12 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 474

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	18 OCT 2022 23:59
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US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3392287

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:22:36

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		05 MAR 2021 09:02:07

US3392287

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 23:04:41

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392287

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 23:04:41

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392287

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392287

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392287

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:10:26

Generated On: 09 Jun 2021 17:22:36

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

Visit date (dd MMM yyyy)	29 MAR 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	VISIT4
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US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 20:10:26

Generated On: 09 Jun 2021 17:22:36

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) _____

US3392287

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 20:10:26

Generated On: 09 Jun 2021 17:22:36

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.

US3392287

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 20:10:26

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 MAR 2021

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

29 MAR 2021 13:30

US3392287

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 29 Apr 2021 20:10:26

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392287

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3392287

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

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

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

Visit date (dd MMM yyyy)	15 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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US3392287

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

Form: Unblinding

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Date of updated informed consent (dd MMM yyyy) 15 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) 15 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 _____

US3392287

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00-23:59)	11:58 (24 HR)
Collection date and time (derived)	15 JAN 2021 11:58

US3392287

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	12:00
Collection Date and Time (derived)	15 JAN 2021 12:00

US3392287

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

AEID	USA-US119-2021-MRNA-1273-P30 1000005
Adverse event	WORSENING CHRONIC ATRIAL FIBRILLATION
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)	08 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	09 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	09 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Number of Days in ICU	
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 Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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	SUBJECT WAS ADMITTED TO THE HOSPITAL OVERNIGHT WITH WORSENING ATRIAL FIBRILLATION. SUBJECT WAS TREATED WITH ABLATION AND SOTALOL.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

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

Yes ☒

No ☐

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

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Name of Medication DULOXENTINE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 60

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 (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Name of Medication FLECAINIDE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 100

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 (2)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 25

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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EAB) (1725)

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Name of Medication RIVAROXABAN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Name of Medication TRAZADONE

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 50

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2019	
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 (6)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Name of Medication TYLENOL [ACETAMINOPHEN]

Prophylaxis Yes ☐
No ☒

Indication HEADACHE, PAIN AT
INJECTION SITE

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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EAB) (1725)

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

	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)	13 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)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Name of Medication SOTALOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING CHRONIC ATRIAL
FIBRILLATION

Dose per administration 60

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

	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)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Name of Medication _____

Prophylaxis Yes ☐
No ☐

Indication _____

Dose per administration _____

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3392287

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 FEB 2021	CARDIAC ABLATION	Adverse Event	

US3392287

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:22:36

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

US3392287

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US119-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:10:25

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US119-2021-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	10/FEB/2021 11:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3392287 (Prod: Benchmark Research - Metairie - PPDS)

US3392287

Form: Participant Creation

Generated On: 09 Jun 2021 17:22:36

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'US3392287'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 15:54:28

US3392287

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:01

US3392287

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 15:54:29

US3392287

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:01

US3392287

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'SCRN'	System	16 Sep 2020 17:12:01

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered (b) (6) 1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 15:54:30

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '65'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'YEARS'	System	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered '65'	System	16 Sep 2020 17:12:32

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'I'	(b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:17

US3392287

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:32

US3392287

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'Sep 2020'	System	16 Sep 2020 17:12:32

US3392287

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered '2020'	System	16 Sep 2020 17:12:32

US3392287

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:32

US3392287

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:32

US3392287

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:32

US3392287

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:32

US3392287

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:32

US3392287

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 15:54:29

US3392287

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'I'	System	16 Sep 2020 17:12:40

US3392287

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:40

US3392287

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:22:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:12:47

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 13:17:43
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'CON MED ECRF DATA UPDATED PER SOURCE DOCUMENTATION.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 21:18:02
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:53:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:53:22
Data point term sent to Coder	System	06 Nov 2020 20:52:35
Coding entries removed.	(b) (4), (b) (6)	06 Nov 2020 20:51:48
User entered 'ATRIAL FIBRILLATION' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:51:48
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 05:09:45
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 17:14:46

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	16 Sep 2020 17:14:46
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 17:14:01
User entered 'A-FIB'	(b) (4), (b) (6)	16 Sep 2020 17:13:24

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'UN Jan 2007'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:13:24

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:13:24

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:13:24

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:13:24

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:13:24

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'Jan 2007'	System	16 Sep 2020 17:13:24

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered '2007'	System	16 Sep 2020 17:13:24

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered empty.	System	16 Sep 2020 17:13:24

US3392287

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered empty.	System	16 Sep 2020 17:13:24

US3392287

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 17:14:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Sep 2020 17:14:46
Data point term sent to Coder	System	16 Sep 2020 17:14:01
User entered 'DEPRESSION'	(b) (4), (b) (6)	16 Sep 2020 17:13:56

US3392287

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'UN Jan 2000'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:13:56

US3392287

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:13:56

US3392287

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:13:56

US3392287

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:13:56

US3392287

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:13:56

US3392287

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'Jan 2000'	System	16 Sep 2020 17:13:56

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Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered '2000'	System	16 Sep 2020 17:13:56

US3392287

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered empty.	System	16 Sep 2020 17:13:56

US3392287

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered empty.	System	16 Sep 2020 17:13:56

US3392287

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Sep 2020 17:15:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 17:15:49
Data point term sent to Coder	System	16 Sep 2020 17:15:04
User entered 'OBESITY'	(b) (4), (b) (6)	16 Sep 2020 17:14:36

US3392287

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'UN Jan 1982'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:14:36

US3392287

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:14:36

US3392287

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:14:36

US3392287

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:14:36

US3392287

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:14:36

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'Jan 1982'	System	16 Sep 2020 17:14:36

US3392287

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered '1982'	System	16 Sep 2020 17:14:36

US3392287

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered empty.	System	16 Sep 2020 17:14:36

US3392287

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered empty.	System	16 Sep 2020 17:14:36

US3392287

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Sep 2020 17:17:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 17:17:41
Data point term sent to Coder	System	16 Sep 2020 17:16:10
User entered 'POST MENOPAUSAL'	(b) (4), (b) (6)	16 Sep 2020 17:15:11

US3392287

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'UN Jan 2010'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:15:11

US3392287

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:15:11

US3392287

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:15:11

US3392287

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:15:11

US3392287

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:15:11

US3392287

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'Jan 2010'	System	16 Sep 2020 17:15:11

US3392287

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered '2010'	System	16 Sep 2020 17:15:11

US3392287

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered empty.	System	16 Sep 2020 17:15:11

US3392287

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered empty.	System	16 Sep 2020 17:15:11

US3392287

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 21:09:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 21:09:23
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:54:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 20:54:22
Data point term sent to Coder	System	06 Nov 2020 20:53:37
User entered 'SLEEP APNEA'	(b) (4), (b) (6)	06 Nov 2020 20:52:58

US3392287

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'UN Jan 2006'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:52:58

US3392287

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:52:58

US3392287

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:52:58

US3392287

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:52:58

US3392287

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:52:58

US3392287

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'Jan 2006'	System	06 Nov 2020 20:52:58

US3392287

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered '2006'	System	06 Nov 2020 20:52:58

US3392287

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered empty.	System	06 Nov 2020 20:52:58

US3392287

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered empty.	System	06 Nov 2020 20:52:58

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '11:16'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered '16 Sep 2020 11:16'	System	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '62' in	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27
DataPoint set to visible.	System	16 Sep 2020 17:12:40

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '250.0' lb	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27
DataPoint set to visible.	System	16 Sep 2020 17:12:40

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered '45.82121'	System	16 Sep 2020 17:16:27
DataPoint set to visible.	System	16 Sep 2020 17:12:40

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'kg/m2'	System	16 Sep 2020 17:16:27
DataPoint set to visible.	System	16 Sep 2020 17:12:40

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '64'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'bpm'	System	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '14'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'breaths/min'	System	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '117'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'mmHg'	System	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '61'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User entered 'mmHg'	System	16 Sep 2020 17:16:27

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06

US3392287

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06

US3392287

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:37

US3392287

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:16:37

US3392287

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:17:25

US3392287

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:17:25

US3392287

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	16 Sep 2020 17:17:25

US3392287

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:22:36

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:17:25

US3392287

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:17:25

US3392287

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:22:36

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:17:25

US3392287

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'UN Jan 2010'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:17:25

US3392287

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:22:36

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:17:25

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered '0'	(b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 11:05:06
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:22:33
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:15

US3392287

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User closed query 'Per CDM: According to CCGs pages 16-17, information is required for Vital Signs Dosing, Physical exam, Pregnancy test (if applicable), Exposure, Immunogenicity Assessment, Central Lab - Nasopharyngeal Swab and Continuing eCRF forms under VID1 section. Please update the missing and incomplete pages for this subject following the CCGs. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 15:03:51
Query 'Per CDM: According to CCGs pages 16-17, information is required for Vital Signs Dosing, Physical exam, Pregnancy test (if applicable), Exposure, Immunogenicity Assessment, Central Lab - Nasopharyngeal Swab and Continuing eCRF forms under VID1 section. Please update the missing and incomplete pages for this subject following the CCGs.	(b) (4), (b) (6)	06 Nov 2020 22:33:14
' answered with 'DATA UPDATED.' (Site from DM).		
User opened query 'Per CDM: According to CCGs pages 16-17, information is required for Vital Signs Dosing, Physical exam, Pregnancy test (if applicable), Exposure, Immunogenicity Assessment, Central Lab - Nasopharyngeal Swab and Continuing eCRF forms under VID1 section. Please update the missing and incomplete pages for this subject following the CCGs. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 22:08:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:18:26

US3392287

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:26

US3392287

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'Clinic (Clinic)' reason for change:	System	06 Nov 2020 22:32:57
Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 22:32:57
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).		
User entered empty.	System	16 Sep 2020 17:18:26
	(b) (4), (b) (6)	16 Sep 2020 17:18:26

US3392287

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'VISIT1'	System	16 Sep 2020 17:18:26

US3392287

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '16 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 16:59:33

US3392287

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '190882'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 16:59:33

US3392287

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	16 Sep 2020 16:59:33

US3392287

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 17:18:48

US3392287

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 17:18:48

US3392287

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:48

US3392287

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:48

US3392287

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:48

US3392287

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:48:23
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:20:44
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:20:43

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '11:00'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered '16 Sep 2020 11:00'	System	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '63'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'bpm'	System	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '16'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'breaths/min'	System	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '117'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'mmHg'	System	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '72'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'mmHg'	System	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
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	06 Nov 2020 20:50:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:50:43
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Nov 2020 20:50:36
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '12:50'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered '16 Sep 2020 12:50'	System	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '64'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'bpm'	System	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '16'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'breaths/min'	System	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '117'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'mmHg'	System	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '61'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'mmHg'	System	06 Nov 2020 20:50:36

US3392287

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:57

US3392287

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:18:57

US3392287

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:20

US3392287

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:20

US3392287

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 17:19:20

US3392287

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 17:19:20

US3392287

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:20

US3392287

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '12:04'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:20

US3392287

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered '16 Sep 2020 12:04'	System	16 Sep 2020 17:19:20

US3392287

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:20

US3392287

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'ONCE'	System	16 Sep 2020 17:19:20

US3392287

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 17:19:20

US3392287

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:39

US3392287

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:39

US3392287

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '11:45'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:39

US3392287

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered '16 Sep 2020 11:45'	System	16 Sep 2020 17:19:39

US3392287

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:22:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:56

US3392287

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Sep 2020 17:19:56

US3392287

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:56

US3392287

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered '11:40'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:56

US3392287

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered '16 Sep 2020 11:40'	System	16 Sep 2020 17:19:56

US3392287

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Sep 2020 17:19:56

US3392287

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:56

US3392287

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:19:56

US3392287

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered empty.	System	16 Sep 2020 17:19:56

US3392287

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:01:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 17:20:03

US3392287

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'I'	System	16 Sep 2020 17:20:03

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:47:36', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15795232-e527-4e17-b972-5f31b0a5f195'	System	16 Sep 2020 17:48:09
User entered 'Yes (Y)'	System	16 Sep 2020 17:48:09

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:48:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15795232-e527-4e17-b972-5f31b0a5f195' User entered '98.1'	System	16 Sep 2020 17:48:09
	System	16 Sep 2020 17:48:09

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:47:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15795232-e527-4e17-b972-5f31b0a5f195'	System	16 Sep 2020 17:48:09
User entered 'No (N)'	System	16 Sep 2020 17:48:09

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:48:07', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15795232-e527-4e17-b972-5f31b0a5f195'	System	16 Sep 2020 17:48:09
User entered '16 Sep 2020 12:48'	System	16 Sep 2020 17:48:09

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Sep 2020 12:24'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Sep 2020 14:54'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:56:10', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd7caa840-511e-4d48-baae-2e598ac59a34' User entered 'Yes (Y)'	System	17 Sep 2020 03:56:37
	System	17 Sep 2020 03:56:37

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:56:22', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd7caa840-511e-4d48-baae-2e598ac59a34' User entered '96.0'	System	17 Sep 2020 03:56:37
	System	17 Sep 2020 03:56:37

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:56:31', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd7caa840-511e-4d48-baae-2e598ac59a34'	System	17 Sep 2020 03:56:37
User entered 'No (N)'	System	17 Sep 2020 03:56:37

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:56:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd7caa840-511e-4d48-baae-2e598ac59a34' User entered '16 Sep 2020 22:56'	System	17 Sep 2020 03:56:37
	System	17 Sep 2020 03:56:37

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Sep 2020 15:49'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 2'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:16:36', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '81100a9c-46c3-44bd-8023-54ea5e5fb0df' User entered 'Yes (Y)'	System	17 Sep 2020 21:17:34
	System	17 Sep 2020 21:17:34

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:17:18', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '81100a9c-46c3-44bd-8023-54ea5e5fb0df' User entered '97.9'	System	17 Sep 2020 21:17:34
	System	17 Sep 2020 21:17:34

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:17:24', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '81100a9c-46c3-44bd-8023-54ea5e5fb0df' User entered 'No (N)'	System	17 Sep 2020 21:17:34
	System	17 Sep 2020 21:17:34

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:17:30', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '81100a9c-46c3-44bd-8023-54ea5e5fb0df' User entered '17 Sep 2020 16:17'	System	17 Sep 2020 21:17:34
	System	17 Sep 2020 21:17:34

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 3'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T23:11:19', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '059afe92-a048-4cc8-9061-d28089366260' User entered 'Yes (Y)'	System	19 Sep 2020 04:11:59
	System	19 Sep 2020 04:11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T23:11:42', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '059afe92-a048-4cc8-9061-d28089366260' User entered '97.9'	System	19 Sep 2020 04:11:59
	System	19 Sep 2020 04:11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T23:11:52', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '059afe92-a048-4cc8-9061-d28089366260' User entered 'No (N)'	System	19 Sep 2020 04:11:59
	System	19 Sep 2020 04:11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T23:11:57', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '059afe92-a048-4cc8-9061-d28089366260' User entered '18 Sep 2020 23:11'	System	19 Sep 2020 04:11:59
	System	19 Sep 2020 04:11:59

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 4'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:47:45', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '8d72f9ca-ab70-4e3f-b87b-9d4ad321c382' User entered 'Yes (Y)'	System	20 Sep 2020 00:48:01
	System	20 Sep 2020 00:48:01

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:47:52', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '8d72f9ca-ab70-4e3f-b87b-9d4ad321c382' User entered '97.7'	System	20 Sep 2020 00:48:01
	System	20 Sep 2020 00:48:01

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:47:56', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '8d72f9ca-ab70-4e3f-b87b-9d4ad321c382'	System	20 Sep 2020 00:48:01
User entered 'No (N)'	System	20 Sep 2020 00:48:01

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:48:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '8d72f9ca-ab70-4e3f-b87b-9d4ad321c382'	System	20 Sep 2020 00:48:01
User entered '19 Sep 2020 19:48'	System	20 Sep 2020 00:48:01

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 5'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:18:19', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '109f570c-0577-4142-a493-747a27298ed0' User entered 'Yes (Y)'	System	21 Sep 2020 00:19:44
	System	21 Sep 2020 00:19:44

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:19:28', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '109f570c-0577-4142-a493-747a27298ed0' User entered '98.6'	System	21 Sep 2020 00:19:44
	System	21 Sep 2020 00:19:44

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:19:33', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '109f570c-0577-4142-a493-747a27298ed0' User entered 'No (N)'	System	21 Sep 2020 00:19:44
	System	21 Sep 2020 00:19:44

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:19:41', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '109f570c-0577-4142-a493-747a27298ed0' User entered '20 Sep 2020 19:19'	System	21 Sep 2020 00:19:44
	System	21 Sep 2020 00:19:44

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 6'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:50:59', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f4e14fa3-0748-45da-ad06-97cf1953e8d1' User entered 'Yes (Y)'	System	22 Sep 2020 02:51:19
	System	22 Sep 2020 02:51:19

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:06', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f4e14fa3-0748-45da-ad06-97cf1953e8d1' User entered '97.4'	System	22 Sep 2020 02:51:19
	System	22 Sep 2020 02:51:19

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:12', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f4e14fa3-0748-45da-ad06-97cf1953e8d1'	System	22 Sep 2020 02:51:19
User entered 'No (N)'	System	22 Sep 2020 02:51:19

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:17', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f4e14fa3-0748-45da-ad06-97cf1953e8d1' User entered '21 Sep 2020 21:51'	System	22 Sep 2020 02:51:19
	System	22 Sep 2020 02:51:19

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 7'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:38:43', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'bab87bfc-e8fc-4b82-be68-09a0454ff7e4' User entered 'Yes (Y)'	System	23 Sep 2020 04:40:13
	System	23 Sep 2020 04:40:13

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:39:47', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'bab87bfc-e8fc-4b82-be68-09a0454ff7e4' User entered '98.6'	System	23 Sep 2020 04:40:13
	System	23 Sep 2020 04:40:13

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:40:04', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'bab87bfc-e8fc-4b82-be68-09a0454ff7e4'	System	23 Sep 2020 04:40:13
User entered 'No (N)'	System	23 Sep 2020 04:40:13

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:40:10', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'bab87bfc-e8fc-4b82-be68-09a0454ff7e4'	System	23 Sep 2020 04:40:13
User entered '22 Sep 2020 23:40'	System	23 Sep 2020 04:40:13

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:44:39', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '131a0ade-7d37-407e-9e1f-0e781d93c65c' User entered 'None (1)'	System	16 Sep 2020 17:45:23
	System	16 Sep 2020 17:45:23

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:44:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '131a0ade-7d37-407e-9e1f-0e781d93c65c' User entered 'No (N)'	System	16 Sep 2020 17:45:23
	System	16 Sep 2020 17:45:23

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:44:54', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '131a0ade-7d37-407e-9e1f-0e781d93c65c' User entered 'No (N)'	System	16 Sep 2020 17:45:23
	System	16 Sep 2020 17:45:23

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:45:09', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '131a0ade-7d37-407e-9e1f-0e781d93c65c' User entered 'None (1)'	System	16 Sep 2020 17:45:23
	System	16 Sep 2020 17:45:23

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:45:17', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '131a0ade-7d37-407e-9e1f-0e781d93c65c' User entered '16 Sep 2020 12:45'	System	16 Sep 2020 17:45:23
	System	16 Sep 2020 17:45:23

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Sep 2020 12:24'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Sep 2020 14:54'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:53:23', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '040dfcbb-f23e-4f77-9c88-bf838d6d4b0c'	System	17 Sep 2020 03:53:56
User entered 'None (1)'	System	17 Sep 2020 03:53:56

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:53:28', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '040dfcbb-f23e-4f77-9c88-bf838d6d4b0c' User entered 'No (N)'	System	17 Sep 2020 03:53:56
	System	17 Sep 2020 03:53:56

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:53:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '040dfcbb-f23e-4f77-9c88-bf838d6d4b0c' User entered 'No (N)'	System	17 Sep 2020 03:53:56
	System	17 Sep 2020 03:53:56

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:53:44', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '040dfcbb-f23e-4f77-9c88-bf838d6d4b0c'	System	17 Sep 2020 03:53:56
User entered 'None (1)'	System	17 Sep 2020 03:53:56

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:53:53', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '040dfcbb-f23e-4f77-9c88-bf838d6d4b0c' User entered '16 Sep 2020 22:53'	System	17 Sep 2020 03:53:56
	System	17 Sep 2020 03:53:56

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Sep 2020 15:49'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 2'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:14:27', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd8afed44-c3d5-4a79-b53a-f37da12f77ea'	System	17 Sep 2020 21:15:33
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 21:15:33

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:14:31', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd8afed44-c3d5-4a79-b53a-f37da12f77ea' User entered 'No (N)'	System	17 Sep 2020 21:15:33
	System	17 Sep 2020 21:15:33

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:15:03', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd8afed44-c3d5-4a79-b53a-f37da12f77ea' User entered 'No (N)'	System	17 Sep 2020 21:15:33
	System	17 Sep 2020 21:15:33

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:15:16', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd8afed44-c3d5-4a79-b53a-f37da12f77ea'	System	17 Sep 2020 21:15:33
User entered 'None (1)'	System	17 Sep 2020 21:15:33

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:15:28', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd8afed44-c3d5-4a79-b53a-f37da12f77ea'	System	17 Sep 2020 21:15:33
User entered '17 Sep 2020 16:15'	System	17 Sep 2020 21:15:33

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 3'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:01:54', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '393c8fd6-7eb4-4890-89cd-d788c8843bac'	System	18 Sep 2020 17:02:57
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 17:02:57

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:01:57', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '393c8fd6-7eb4-4890-89cd-d788c8843bac' User entered 'No (N)'	System	18 Sep 2020 17:02:57
	System	18 Sep 2020 17:02:57

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:02:10', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '393c8fd6-7eb4-4890-89cd-d788c8843bac' User entered 'No (N)'	System	18 Sep 2020 17:02:57
	System	18 Sep 2020 17:02:57

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:02:20', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '393c8fd6-7eb4-4890-89cd-d788c8843bac'	System	18 Sep 2020 17:02:57
User entered 'None (1)'	System	18 Sep 2020 17:02:57

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:02:27', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '393c8fd6-7eb4-4890-89cd-d788c8843bac' User entered '18 Sep 2020 12:02'	System	18 Sep 2020 17:02:57
	System	18 Sep 2020 17:02:57

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 4'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:40:24', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2b363b94-2a12-4cc2-a5b2-7e37bb71b37c'	System	20 Sep 2020 00:40:46
User entered 'None (1)'	System	20 Sep 2020 00:40:46

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:40:33', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2b363b94-2a12-4cc2-a5b2-7e37bb71b37c' User entered 'No (N)'	System	20 Sep 2020 00:40:46
	System	20 Sep 2020 00:40:46

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:40:37', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2b363b94-2a12-4cc2-a5b2-7e37bb71b37c' User entered 'No (N)'	System	20 Sep 2020 00:40:46
	System	20 Sep 2020 00:40:46

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:40:40', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2b363b94-2a12-4cc2-a5b2-7e37bb71b37c'	System	20 Sep 2020 00:40:46
User entered 'None (1)'	System	20 Sep 2020 00:40:46

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:40:44', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2b363b94-2a12-4cc2-a5b2-7e37bb71b37c' User entered '19 Sep 2020 19:40'	System	20 Sep 2020 00:40:46
	System	20 Sep 2020 00:40:46

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 5'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:16:30', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '75886695-7874-49f1-9b60-c2c26a0287ea' User entered 'None (1)'	System	21 Sep 2020 00:16:46
	System	21 Sep 2020 00:16:46

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:16:33', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '75886695-7874-49f1-9b60-c2c26a0287ea' User entered 'No (N)'	System	21 Sep 2020 00:16:46
	System	21 Sep 2020 00:16:46

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:16:36', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '75886695-7874-49f1-9b60-c2c26a0287ea' User entered 'No (N)'	System	21 Sep 2020 00:16:46
	System	21 Sep 2020 00:16:46

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:16:40', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '75886695-7874-49f1-9b60-c2c26a0287ea' User entered 'None (1)'	System	21 Sep 2020 00:16:46
	System	21 Sep 2020 00:16:46

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:16:44', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '75886695-7874-49f1-9b60-c2c26a0287ea' User entered '20 Sep 2020 19:16'	System	21 Sep 2020 00:16:46
	System	21 Sep 2020 00:16:46

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 6'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:25', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '965d9199-477c-42dd-afb1-3b2ea661c718'	System	22 Sep 2020 02:51:40
User entered 'None (1)'	System	22 Sep 2020 02:51:40

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:28', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '965d9199-477c-42dd-afb1-3b2ea661c718' User entered 'No (N)'	System	22 Sep 2020 02:51:40
	System	22 Sep 2020 02:51:40

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:32', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '965d9199-477c-42dd-afb1-3b2ea661c718' User entered 'No (N)'	System	22 Sep 2020 02:51:40
	System	22 Sep 2020 02:51:40

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '965d9199-477c-42dd-afb1-3b2ea661c718'	System	22 Sep 2020 02:51:40
User entered 'None (1)'	System	22 Sep 2020 02:51:40

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:38', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '965d9199-477c-42dd-afb1-3b2ea661c718' User entered '21 Sep 2020 21:51'	System	22 Sep 2020 02:51:40
	System	22 Sep 2020 02:51:40

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 7'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:04', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1fbfcf2d-904d-4b09-b725-6e5785bb589e' User entered 'None (1)'	System	23 Sep 2020 04:37:24
	System	23 Sep 2020 04:37:24

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:12', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1fbfcf2d-904d-4b09-b725-6e5785bb589e' User entered 'No (N)'	System	23 Sep 2020 04:37:24
	System	23 Sep 2020 04:37:24

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:15', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1fbfcf2d-904d-4b09-b725-6e5785bb589e' User entered 'No (N)'	System	23 Sep 2020 04:37:24
	System	23 Sep 2020 04:37:24

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:18', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1fbfcf2d-904d-4b09-b725-6e5785bb589e' User entered 'None (1)'	System	23 Sep 2020 04:37:24
	System	23 Sep 2020 04:37:24

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:21', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1fbfcf2d-904d-4b09-b725-6e5785bb589e' User entered '22 Sep 2020 23:37'	System	23 Sep 2020 04:37:24
	System	23 Sep 2020 04:37:24

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:45:26', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '27477c80-8580-442d-af0d-80137a6135e9' User entered 'None (0)'	System	16 Sep 2020 17:46:06
	System	16 Sep 2020 17:46:06

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:45:30', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '27477c80-8580-442d-af0d-80137a6135e9' User entered 'None (0)'	System	16 Sep 2020 17:46:06
	System	16 Sep 2020 17:46:06

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:45:34', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '27477c80-8580-442d-af0d-80137a6135e9' User entered 'None (0)'	System	16 Sep 2020 17:46:06
	System	16 Sep 2020 17:46:06

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:45:40', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '27477c80-8580-442d-af0d-80137a6135e9' User entered 'None (0)'	System	16 Sep 2020 17:46:06
	System	16 Sep 2020 17:46:06

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:45:44', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '27477c80-8580-442d-af0d-80137a6135e9' User entered 'None (0)'	System	16 Sep 2020 17:46:06
	System	16 Sep 2020 17:46:06

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:45:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '27477c80-8580-442d-af0d-80137a6135e9' User entered 'None (0)'	System	16 Sep 2020 17:46:06
	System	16 Sep 2020 17:46:06

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:45:54', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '27477c80-8580-442d-af0d-80137a6135e9' User entered 'No (N)'	System	16 Sep 2020 17:46:06
	System	16 Sep 2020 17:46:06

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T12:46:02', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '27477c80-8580-442d-af0d-80137a6135e9' User entered '16 Sep 2020 12:46'	System	16 Sep 2020 17:46:06
	System	16 Sep 2020 17:46:06

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Sep 2020 12:24'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Sep 2020 14:54'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:54:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0e0da281-5c40-4e80-bc36-1b16647be217' User entered 'None (0)'	System	17 Sep 2020 03:54:37
	System	17 Sep 2020 03:54:37

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:54:04', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0e0da281-5c40-4e80-bc36-1b16647be217' User entered 'None (0)'	System	17 Sep 2020 03:54:37
	System	17 Sep 2020 03:54:37

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:54:09', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0e0da281-5c40-4e80-bc36-1b16647be217' User entered 'None (0)'	System	17 Sep 2020 03:54:37
	System	17 Sep 2020 03:54:37

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:54:16', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0e0da281-5c40-4e80-bc36-1b16647be217' User entered 'None (0)'	System	17 Sep 2020 03:54:37
	System	17 Sep 2020 03:54:37

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:54:19', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0e0da281-5c40-4e80-bc36-1b16647be217' User entered 'None (0)'	System	17 Sep 2020 03:54:37
	System	17 Sep 2020 03:54:37

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:54:23', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0e0da281-5c40-4e80-bc36-1b16647be217' User entered 'None (0)'	System	17 Sep 2020 03:54:37
	System	17 Sep 2020 03:54:37

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:54:30', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0e0da281-5c40-4e80-bc36-1b16647be217'	System	17 Sep 2020 03:54:37
User entered 'No (N)'	System	17 Sep 2020 03:54:37

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-16T22:54:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0e0da281-5c40-4e80-bc36-1b16647be217' User entered '16 Sep 2020 22:54'	System	17 Sep 2020 03:54:37
	System	17 Sep 2020 03:54:37

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Sep 2020 15:49'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 2'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:15:39', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '33452530-6de5-464f-ae9b-adcf9896baf3'	System	17 Sep 2020 21:16:18
User entered 'No interference with activity (1)'	System	17 Sep 2020 21:16:18

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:15:44', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '33452530-6de5-464f-ae9b-adcf9896baf3' User entered 'None (0)'	System	17 Sep 2020 21:16:18
	System	17 Sep 2020 21:16:18

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:15:48', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '33452530-6de5-464f-ae9b-adcf9896baf3' User entered 'None (0)'	System	17 Sep 2020 21:16:18
	System	17 Sep 2020 21:16:18

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:15:56', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '33452530-6de5-464f-ae9b-adcf9896baf3' User entered 'None (0)'	System	17 Sep 2020 21:16:18
	System	17 Sep 2020 21:16:18

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:15:59', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '33452530-6de5-464f-ae9b-adcf9896baf3' User entered 'None (0)'	System	17 Sep 2020 21:16:18
	System	17 Sep 2020 21:16:18

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:16:02', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '33452530-6de5-464f-ae9b-adcf9896baf3' User entered 'None (0)'	System	17 Sep 2020 21:16:18
	System	17 Sep 2020 21:16:18

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:16:06', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '33452530-6de5-464f-ae9b-adcf9896baf3' User entered 'No (N)'	System	17 Sep 2020 21:16:18
	System	17 Sep 2020 21:16:18

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-17T16:16:14', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '33452530-6de5-464f-ae9b-adcf9896baf3'	System	17 Sep 2020 21:16:18
User entered '17 Sep 2020 16:16'	System	17 Sep 2020 21:16:18

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 3'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:02:36', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c5880cd4-4079-4605-b260-04086d3b8cef'	System	18 Sep 2020 17:04:27
User entered 'No interference with activity (1)'	System	18 Sep 2020 17:04:27

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:02:50', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c5880cd4-4079-4605-b260-04086d3b8cef' User entered 'None (0)'	System	18 Sep 2020 17:04:27
	System	18 Sep 2020 17:04:27

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:03:17', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c5880cd4-4079-4605-b260-04086d3b8cef'	System	18 Sep 2020 17:04:27
User entered 'No interference with activity (1)'	System	18 Sep 2020 17:04:27

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:03:45', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c5880cd4-4079-4605-b260-04086d3b8cef'	System	18 Sep 2020 17:04:27
User entered 'No interference with activity (1)'	System	18 Sep 2020 17:04:27

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:03:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c5880cd4-4079-4605-b260-04086d3b8cef' User entered 'None (0)'	System	18 Sep 2020 17:04:27
	System	18 Sep 2020 17:04:27

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:03:53', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c5880cd4-4079-4605-b260-04086d3b8cef' User entered 'None (0)'	System	18 Sep 2020 17:04:27
	System	18 Sep 2020 17:04:27

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:04:17', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c5880cd4-4079-4605-b260-04086d3b8cef' User entered 'No (N)'	System	18 Sep 2020 17:04:27
	System	18 Sep 2020 17:04:27

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-18T12:04:21', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c5880cd4-4079-4605-b260-04086d3b8cef' User entered '18 Sep 2020 12:04'	System	18 Sep 2020 17:04:27
	System	18 Sep 2020 17:04:27

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 4'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:41:02', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '844ed710-b6c9-451f-b608-bbedbb2eda25' User entered 'None (0)'	System	20 Sep 2020 00:41:42
	System	20 Sep 2020 00:41:42

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:41:07', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '844ed710-b6c9-451f-b608-bbedbb2eda25'	System	20 Sep 2020 00:41:42
User entered 'No interference with activity (1)'	System	20 Sep 2020 00:41:42

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:41:12', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '844ed710-b6c9-451f-b608-bbedbb2eda25' User entered 'None (0)'	System	20 Sep 2020 00:41:42
	System	20 Sep 2020 00:41:42

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:41:20', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '844ed710-b6c9-451f-b608-bbedbb2eda25' User entered 'None (0)'	System	20 Sep 2020 00:41:42
	System	20 Sep 2020 00:41:42

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:41:23', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '844ed710-b6c9-451f-b608-bbedbb2eda25' User entered 'None (0)'	System	20 Sep 2020 00:41:42
	System	20 Sep 2020 00:41:42

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:41:26', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '844ed710-b6c9-451f-b608-bbedbb2eda25' User entered 'None (0)'	System	20 Sep 2020 00:41:42
	System	20 Sep 2020 00:41:42

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:41:32', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '844ed710-b6c9-451f-b608-bbedbb2eda25' User entered 'No (N)'	System	20 Sep 2020 00:41:42
	System	20 Sep 2020 00:41:42

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-19T19:41:40', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '844ed710-b6c9-451f-b608-bbedbb2eda25' User entered '19 Sep 2020 19:41'	System	20 Sep 2020 00:41:42
	System	20 Sep 2020 00:41:42

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 5'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:16:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f884e075-f1fd-4cba-9532-f8b3c7c6a265'	System	21 Sep 2020 00:17:10
User entered 'None (0)'	System	21 Sep 2020 00:17:10

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:16:51', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f884e075-f1fd-4cba-9532-f8b3c7c6a265' User entered 'None (0)'	System	21 Sep 2020 00:17:10
	System	21 Sep 2020 00:17:10

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:16:54', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f884e075-f1fd-4cba-9532-f8b3c7c6a265' User entered 'None (0)'	System	21 Sep 2020 00:17:10
	System	21 Sep 2020 00:17:10

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:16:56', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f884e075-f1fd-4cba-9532-f8b3c7c6a265' User entered 'None (0)'	System	21 Sep 2020 00:17:10
	System	21 Sep 2020 00:17:10

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:16:59', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f884e075-f1fd-4cba-9532-f8b3c7c6a265' User entered 'None (0)'	System	21 Sep 2020 00:17:10
	System	21 Sep 2020 00:17:10

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:17:01', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f884e075-f1fd-4cba-9532-f8b3c7c6a265' User entered 'None (0)'	System	21 Sep 2020 00:17:10
	System	21 Sep 2020 00:17:10

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:17:04', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f884e075-f1fd-4cba-9532-f8b3c7c6a265'	System	21 Sep 2020 00:17:10
User entered 'No (N)'	System	21 Sep 2020 00:17:10

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-20T19:17:07', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f884e075-f1fd-4cba-9532-f8b3c7c6a265'	System	21 Sep 2020 00:17:10
User entered '20 Sep 2020 19:17'	System	21 Sep 2020 00:17:10

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 6'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:47', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '96fc5852-43f3-413c-9700-45cd5d107be6'	System	22 Sep 2020 02:52:23
User entered 'No interference with activity (1)'	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:52', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '96fc5852-43f3-413c-9700-45cd5d107be6' User entered 'None (0)'	System	22 Sep 2020 02:52:23
	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:55', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '96fc5852-43f3-413c-9700-45cd5d107be6' User entered 'None (0)'	System	22 Sep 2020 02:52:23
	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:51:58', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '96fc5852-43f3-413c-9700-45cd5d107be6' User entered 'None (0)'	System	22 Sep 2020 02:52:23
	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:52:11', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '96fc5852-43f3-413c-9700-45cd5d107be6'	System	22 Sep 2020 02:52:23
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:52:14', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '96fc5852-43f3-413c-9700-45cd5d107be6' User entered 'None (0)'	System	22 Sep 2020 02:52:23
	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:52:18', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '96fc5852-43f3-413c-9700-45cd5d107be6' User entered 'No (N)'	System	22 Sep 2020 02:52:23
	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-21T21:52:21', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '96fc5852-43f3-413c-9700-45cd5d107be6'	System	22 Sep 2020 02:52:23
User entered '21 Sep 2020 21:52'	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 7'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:31', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0c87619f-7555-401f-a182-0850d33b323a'	System	23 Sep 2020 04:38:04
User entered 'No interference with activity (1)'	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0c87619f-7555-401f-a182-0850d33b323a'	System	23 Sep 2020 04:38:04
User entered 'No interference with activity (1)'	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:38', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0c87619f-7555-401f-a182-0850d33b323a' User entered 'None (0)'	System	23 Sep 2020 04:38:04
	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:41', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0c87619f-7555-401f-a182-0850d33b323a' User entered 'None (0)'	System	23 Sep 2020 04:38:04
	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:44', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0c87619f-7555-401f-a182-0850d33b323a' User entered 'None (0)'	System	23 Sep 2020 04:38:04
	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:46', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0c87619f-7555-401f-a182-0850d33b323a' User entered 'None (0)'	System	23 Sep 2020 04:38:04
	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:37:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0c87619f-7555-401f-a182-0850d33b323a' User entered 'No (N)'	System	23 Sep 2020 04:38:04
	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-22T23:38:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0c87619f-7555-401f-a182-0850d33b323a' User entered '22 Sep 2020 23:38'	System	23 Sep 2020 04:38:04
	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	22 Sep 2020 02:52:23
User entered 'Day 8'	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-24T02:57:44', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '62498a8f-6c9c-4ce9-a0cd-4a109302490a' User entered 'None (0)'	System	24 Sep 2020 07:57:57
	System	24 Sep 2020 07:57:57

US3392287

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-24T02:57:54', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '62498a8f-6c9c-4ce9-a0cd-4a109302490a' User entered '24 Sep 2020 02:57'	System	24 Sep 2020 07:57:57
	System	24 Sep 2020 07:57:57

US3392287

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	23 Sep 2020 04:38:04
User entered 'Day 8'	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-24T02:58:07', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ebdaec6d-3e46-4375-a474-2b251958642c' User entered 'None (0)'	System	24 Sep 2020 07:58:15
	System	24 Sep 2020 07:58:15

US3392287

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-24T02:58:13', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ebdaec6d-3e46-4375-a474-2b251958642c' User entered '24 Sep 2020 02:58'	System	24 Sep 2020 07:58:15
	System	24 Sep 2020 07:58:15

US3392287

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 04:38:04

US3392287

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	22 Sep 2020 02:52:23
User entered 'Day 8'	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-24T02:58:20', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '12c52309-bd8e-4cef-809b-c34014b69c97' User entered 'No (N)'	System	24 Sep 2020 07:58:30
	System	24 Sep 2020 07:58:30

US3392287

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-09-24T02:58:25', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '12c52309-bd8e-4cef-809b-c34014b69c97'	System	24 Sep 2020 07:58:30
User entered '24 Sep 2020 02:58'	System	24 Sep 2020 07:58:30

US3392287

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 02:52:23

US3392287

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 02:52:23

US3392287

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:14:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:27:20

US3392287

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:14:32
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:27:20

US3392287

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:14:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:27:20

US3392287

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:14:32
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:27:20

US3392287

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:14:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 17:27:24

US3392287

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'I'	System	24 Sep 2020 17:27:24

US3392287

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:40:44
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	01 Oct 2020 15:46:01
User entered 'Yes (Y)'	System	01 Oct 2020 15:45:51
	(b) (4), (b) (6)	01 Oct 2020 15:45:51

US3392287

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:40:44
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:46:01
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:45:51

US3392287

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:40:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:45:51

US3392287

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:40:44
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:45:51

US3392287

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:40:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 15:45:43

US3392287

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:23:14
User entered 'I'	System	01 Oct 2020 15:45:43

US3392287

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:57
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:21:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:37:39

US3392287

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:57
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:21:20
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:37:39

US3392287

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:57
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:21:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:37:39

US3392287

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:57
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:21:20
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:37:39

US3392287

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:57
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:21:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 20:37:44

US3392287

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:57
User entered 'I'	System	07 Oct 2020 20:37:44

US3392287

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:59
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	12 Oct 2020 15:31:45

US3392287

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:59
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '12 Oct 2020'	Brandon Illickal (b) (4)	12 Oct 2020 15:31:45

US3392287

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:59
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'Clinic (Clinic)'	Brandon Illickal (b) (4)	12 Oct 2020 15:31:45

US3392287

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:59
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'VISIT2'	System	12 Oct 2020 15:31:45

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '12 Oct 2020'	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '10:15'	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '12 Oct 2020 10:15'	System	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '98.2' F	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '64'	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'bpm'	System	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '16'	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'breaths/min'	System	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '146'	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'mmHg'	System	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '80'	(b) (4), (b) (6)	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'mmHg'	System	09 Dec 2020 22:17:31

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '12 Oct 2020'	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '11:06'	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '12 Oct 2020 11:06'	System	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '98.3' F	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '67'	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'bpm'	System	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '16'	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'breaths/min'	System	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '132'	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'mmHg'	System	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '73'	(b) (4), (b) (6)	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:35:05
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'mmHg'	System	09 Dec 2020 22:18:28

US3392287

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'No (N)'	Brandon Illickal (b) (4)	12 Oct 2020 15:34:48

US3392287

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:43
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	Brandon Illickal (b) (4)	12 Oct 2020 15:34:48

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User closed query 'Per CDM: Please consider to update 'Vital Signs-Dosing' at this visit.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 14:48:57
Query 'Per CDM: Please consider to update 'Vital Signs-Dosing' at this visit.' answered with 'Vital Signs- Dosing updated. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 22:19:09
User opened query 'Per CDM: Please consider to update 'Vital Signs-Dosing' at this visit.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 12:34:43
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	12 Oct 2020 15:35:02

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	Brandon Illickal (b) (4)	12 Oct 2020 15:35:02

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	Brandon Illickal (b) (4)	12 Oct 2020 15:35:02

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:27
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'MRNA-1273 OR PLACEBO'	System	12 Oct 2020 15:35:02

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '12 Oct 2020'	Brandon Illickal (b) (4)	12 Oct 2020 15:35:02

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '10:33'	Brandon Illickal (b) (4)	12 Oct 2020 15:35:02

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:27
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '12 Oct 2020 10:33'	System	12 Oct 2020 15:35:02

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'Left Arm (LEFT ARM)'	Brandon Illickal (b) (4)	12 Oct 2020 15:35:02

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:27
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'ONCE'	System	12 Oct 2020 15:35:02

US3392287

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:27
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'INTRAMUSCULAR'	System	12 Oct 2020 15:35:02

US3392287

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	12 Oct 2020 15:35:17

US3392287

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '12 Oct 2020'	Brandon Illickal (b) (4)	12 Oct 2020 15:35:17

US3392287

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '10:20'	Brandon Illickal (b) (4)	12 Oct 2020 15:35:17

US3392287

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:55
Data hard unlocked.	(b) (4), (b) (6)	30 Apr 2021 08:32:10
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '12 Oct 2020 10:20'	System	12 Oct 2020 15:35:17

US3392287

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:22:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:49:58
User entered '12 Oct 2020'	(b) (4)	12 Oct 2020 15:35:32
	Brandon Illickal (b) (4)	

US3392287

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brandon Illickal (b) (4)	12 Oct 2020 15:35:32

US3392287

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:49:58
User entered 'Yes (Y)'	(b) (4)	12 Oct 2020 15:35:32
	Brandon Illickal (b) (4)	

US3392287

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:49:58
User entered '10:16'	(b) (4)	12 Oct 2020 15:35:32

US3392287

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '12 Oct 2020 10:16'	System	12 Oct 2020 15:35:32

US3392287

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brandon Illickal (b) (4)	12 Oct 2020 15:35:32

US3392287

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:49:58
User entered 'No (N)'	(b) (4)	12 Oct 2020 15:35:32
	Brandon Illickal (b) (4)	

US3392287

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:49:58
User entered empty.	(b) (4)	12 Oct 2020 15:35:32
	Brandon Illickal (b) (4)	

US3392287

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:22:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	System	12 Oct 2020 15:35:32

US3392287

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:49:58
User entered 'Yes (Y)'	(b) (4)	12 Oct 2020 15:35:55

US3392287

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'I'	System	12 Oct 2020 15:35:55

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:00:48', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'b82a54a1-41cf-423a-a0ad-fdc7649fb66a' User entered 'Yes (Y)'	System	12 Oct 2020 16:01:29
	System	12 Oct 2020 16:01:29

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:00:58', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'b82a54a1-41cf-423a-a0ad-fdc7649fb66a' User entered '98.3'	System	12 Oct 2020 16:01:29
	System	12 Oct 2020 16:01:29

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:01:04', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'b82a54a1-41cf-423a-a0ad-fdc7649fb66a' User entered 'No (N)'	System	12 Oct 2020 16:01:29
	System	12 Oct 2020 16:01:29

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:01:19', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'b82a54a1-41cf-423a-a0ad-fdc7649fb66a' User entered '12 Oct 2020 11:01'	System	12 Oct 2020 16:01:29
	System	12 Oct 2020 16:01:29

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '12 Oct 2020 10:53'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '12 Oct 2020 13:23'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:17:17', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e7c170d-1550-49a9-81bd-ed5bcb9a1efa' User entered 'Yes (Y)'	System	13 Oct 2020 01:17:57
	System	13 Oct 2020 01:17:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:17:23', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e7c170d-1550-49a9-81bd-ed5bcb9a1efa' User entered '97.8'	System	13 Oct 2020 01:17:57
	System	13 Oct 2020 01:17:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:17:27', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e7c170d-1550-49a9-81bd-ed5bcb9a1efa' User entered 'Yes (Y)'	System	13 Oct 2020 01:17:57
	System	13 Oct 2020 01:17:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
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 'con meds updated' (Site from System).	(b) (4), (b) (6)	05 Jan 2021 09:40:41
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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:17:38', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e7c170d-1550-49a9-81bd-ed5bcb9a1efa' User entered '1'	Brandon Illickal (b) (4)	05 Jan 2021 03:07:27
	System	13 Oct 2020 01:17:57
	System	13 Oct 2020 01:17:57
	System	13 Oct 2020 01:17:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:17:38', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e7c170d-1550-49a9-81bd-ed5bcb9a1efa' User entered '0'	System	13 Oct 2020 01:17:57
	System	13 Oct 2020 01:17:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:17:54', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e7c170d-1550-49a9-81bd-ed5bcb9a1efa' User entered '12 Oct 2020 20:17'	System	13 Oct 2020 01:17:57
	System	13 Oct 2020 01:17:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '12 Oct 2020 14:18'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 2'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:11:21', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '78b02adb-617f-421d-a9f0-12c0e8ac107d' User entered 'Yes (Y)'	System	14 Oct 2020 03:13:04
	System	14 Oct 2020 03:13:04

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:12:32', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '78b02adb-617f-421d-a9f0-12c0e8ac107d' User entered '99.3'	System	14 Oct 2020 03:13:04
	System	14 Oct 2020 03:13:04

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:12:37', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '78b02adb-617f-421d-a9f0-12c0e8ac107d' User entered 'Yes (Y)'	System	14 Oct 2020 03:13:04
	System	14 Oct 2020 03:13:04

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
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 'con meds updated' (Site from System).	(b) (4), (b) (6)	05 Jan 2021 09:40:46
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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:12:55', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '78b02adb-617f-421d-a9f0-12c0e8ac107d' User entered '1'	Brandon Illickal (b) (4)	05 Jan 2021 03:07:34
	System	14 Oct 2020 03:13:04
	System	14 Oct 2020 03:13:04
	System	14 Oct 2020 03:13:04

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:12:55', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '78b02adb-617f-421d-a9f0-12c0e8ac107d' User entered '0'	System	14 Oct 2020 03:13:04
	System	14 Oct 2020 03:13:04

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:12:59', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '78b02adb-617f-421d-a9f0-12c0e8ac107d' User entered '13 Oct 2020 22:12'	System	14 Oct 2020 03:13:04
	System	14 Oct 2020 03:13:04

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 3'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:29:53', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '7cea634a-3e3d-4006-9d98-8927695fbe12'	System	14 Oct 2020 22:31:09
User entered 'Yes (Y)'	System	14 Oct 2020 22:31:09

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:30:50', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '7cea634a-3e3d-4006-9d98-8927695fbe12' User entered '97.2'	System	14 Oct 2020 22:31:09
	System	14 Oct 2020 22:31:09

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:30:55', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '7cea634a-3e3d-4006-9d98-8927695fbe12'	System	14 Oct 2020 22:31:09
User entered 'Yes (Y)'	System	14 Oct 2020 22:31:09

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
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 'con meds updated' (Site from System).	(b) (4), (b) (6)	05 Jan 2021 09:40:52
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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:31:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '7cea634a-3e3d-4006-9d98-8927695fbc12' User entered '1'	Brandon Illickal (b) (4)	05 Jan 2021 03:07:42
	System	14 Oct 2020 22:31:09
	System	14 Oct 2020 22:31:09
	System	14 Oct 2020 22:31:09

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:31:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '7cea634a-3e3d-4006-9d98-8927695fbe12' User entered '0'	System	14 Oct 2020 22:31:09
	System	14 Oct 2020 22:31:09

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:31:05', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '7cea634a-3e3d-4006-9d98-8927695fbe12'	System	14 Oct 2020 22:31:09
User entered '14 Oct 2020 17:31'	System	14 Oct 2020 22:31:09

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 4'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:19:32', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2c24c79b-3fa1-41de-865e-1760dc21bacc' User entered 'Yes (Y)'	System	16 Oct 2020 06:19:57
	System	16 Oct 2020 06:19:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:19:38', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2c24c79b-3fa1-41de-865e-1760dc21bacc' User entered '97.7'	System	16 Oct 2020 06:19:57
	System	16 Oct 2020 06:19:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:19:45', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2c24c79b-3fa1-41de-865e-1760dc21bacc' User entered 'Yes (Y)'	System	16 Oct 2020 06:19:57
	System	16 Oct 2020 06:19:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
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 'con meds updated' (Site from System).	(b) (4), (b) (6)	05 Jan 2021 09:40:57
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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:19:51', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2c24c79b-3fa1-41de-865e-1760dc21bacc' User entered '1'	Brandon Illickal (b) (4)	05 Jan 2021 03:07:49
	System	16 Oct 2020 06:19:57
	System	16 Oct 2020 06:19:57
	System	16 Oct 2020 06:19:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:19:51', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2c24c79b-3fa1-41de-865e-1760dc21bacc' User entered '0'	System	16 Oct 2020 06:19:57
	System	16 Oct 2020 06:19:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:19:55', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2c24c79b-3fa1-41de-865e-1760dc21bacc' User entered '16 Oct 2020 01:19'	System	16 Oct 2020 06:19:57
	System	16 Oct 2020 06:19:57

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 5'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:45:56', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ae7e5595-e824-497e-aea2-07b5225eea45'	System	17 Oct 2020 04:47:10
User entered 'Yes (Y)'	System	17 Oct 2020 04:47:10

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:46:56', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ae7e5595-e824-497e-aea2-07b5225eea45' User entered '98.8'	System	17 Oct 2020 04:47:10
	System	17 Oct 2020 04:47:10

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:47:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ae7e5595-e824-497e-aea2-07b5225eea45'	System	17 Oct 2020 04:47:10
User entered 'No (N)'	System	17 Oct 2020 04:47:10

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:47:03', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ae7e5595-e824-497e-aea2-07b5225eea45' User entered '16 Oct 2020 23:47'	System	17 Oct 2020 04:47:10
	System	17 Oct 2020 04:47:10

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 6'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:05:11', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a3cda379-d3c9-45ec-ba67-db266f973f9b' User entered 'Yes (Y)'	System	18 Oct 2020 04:05:49
	System	18 Oct 2020 04:05:49

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:05:20', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a3cda379-d3c9-45ec-ba67-db266f973f9b' User entered '96.6'	System	18 Oct 2020 04:05:49
	System	18 Oct 2020 04:05:49

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:05:32', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a3cda379-d3c9-45ec-ba67-db266f973f9b' User entered 'Yes (Y)'	System	18 Oct 2020 04:05:49
	System	18 Oct 2020 04:05:49

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:05:41', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a3cda379-d3c9-45ec-ba67-db266f973f9b' User entered '0'	System	18 Oct 2020 04:05:49
	System	18 Oct 2020 04:05:49

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'con meds updated' (Site from System).	(b) (4), (b) (6)	05 Jan 2021 09:41:53
User opened query 'Per the participant response, medication was taken to prevent 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:05:41', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a3cda379-d3c9-45ec-ba67-db266f973f9b' User entered '1'	Brandon Illickal (b) (4)	05 Jan 2021 03:08:03
	System	18 Oct 2020 04:05:49
	System	18 Oct 2020 04:05:49
	System	18 Oct 2020 04:05:49

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:05:44', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a3cda379-d3c9-45ec-ba67-db266f973f9b' User entered '17 Oct 2020 23:05'	System	18 Oct 2020 04:05:49
	System	18 Oct 2020 04:05:49

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 7'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:56:08', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '39762445-24bf-4f02-9254-dcb97b9cbd10' User entered 'Yes (Y)'	System	19 Oct 2020 04:56:41
	System	19 Oct 2020 04:56:41

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:56:31', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '39762445-24bf-4f02-9254-dcb97b9cbd10' User entered '98.5'	System	19 Oct 2020 04:56:41
	System	19 Oct 2020 04:56:41

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:56:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '39762445-24bf-4f02-9254-dcb97b9cbd10' User entered 'No (N)'	System	19 Oct 2020 04:56:41
	System	19 Oct 2020 04:56:41

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:56:38', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '39762445-24bf-4f02-9254-dcb97b9cbd10' User entered '18 Oct 2020 23:56'	System	19 Oct 2020 04:56:41
	System	19 Oct 2020 04:56:41

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:01:31', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '43124ca3-bb34-4751-9768-dea8587874f5' User entered 'None (1)'	System	12 Oct 2020 16:02:00
	System	12 Oct 2020 16:02:00

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:01:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '43124ca3-bb34-4751-9768-dea8587874f5' User entered 'No (N)'	System	12 Oct 2020 16:02:00
	System	12 Oct 2020 16:02:00

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:01:39', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '43124ca3-bb34-4751-9768-dea8587874f5' User entered 'No (N)'	System	12 Oct 2020 16:02:00
	System	12 Oct 2020 16:02:00

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:01:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '43124ca3-bb34-4751-9768-dea8587874f5' User entered 'None (1)'	System	12 Oct 2020 16:02:00
	System	12 Oct 2020 16:02:00

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:01:52', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '43124ca3-bb34-4751-9768-dea8587874f5' User entered '12 Oct 2020 11:01'	System	12 Oct 2020 16:02:00
	System	12 Oct 2020 16:02:00

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '12 Oct 2020 10:53'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '12 Oct 2020 13:23'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:18:05', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e3d3cf9-3258-4716-8a7f-d4eef1ed8912'	System	13 Oct 2020 01:18:38
User entered 'None (1)'	System	13 Oct 2020 01:18:38

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:18:12', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e3d3cf9-3258-4716-8a7f-d4eef1ed8912'	System	13 Oct 2020 01:18:38
User entered 'No (N)'	System	13 Oct 2020 01:18:38

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:18:20', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e3d3cf9-3258-4716-8a7f-d4eef1ed8912'	System	13 Oct 2020 01:18:38
User entered 'No (N)'	System	13 Oct 2020 01:18:38

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:18:30', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e3d3cf9-3258-4716-8a7f-d4eef1ed8912'	System	13 Oct 2020 01:18:38
User entered 'None (1)'	System	13 Oct 2020 01:18:38

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:18:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5e3d3cf9-3258-4716-8a7f-d4eef1ed8912'	System	13 Oct 2020 01:18:38
User entered '12 Oct 2020 20:18'	System	13 Oct 2020 01:18:38

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '12 Oct 2020 14:18'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 2'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:09:50', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '61ed092a-08a1-4a20-89e8-6c7b7cddb94a'	System	14 Oct 2020 03:10:22
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	14 Oct 2020 03:10:22

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:09:53', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '61ed092a-08a1-4a20-89e8-6c7b7cddb94a' User entered 'No (N)'	System	14 Oct 2020 03:10:22
	System	14 Oct 2020 03:10:22

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:01', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '61ed092a-08a1-4a20-89e8-6c7b7cddb94a' User entered 'No (N)'	System	14 Oct 2020 03:10:22
	System	14 Oct 2020 03:10:22

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:07', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '61ed092a-08a1-4a20-89e8-6c7b7cddb94a' User entered 'None (1)'	System	14 Oct 2020 03:10:22
	System	14 Oct 2020 03:10:22

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:16', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '61ed092a-08a1-4a20-89e8-6c7b7cddb94a' User entered '13 Oct 2020 22:10'	System	14 Oct 2020 03:10:22
	System	14 Oct 2020 03:10:22

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 3'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:27:28', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a9689a3a-fc11-4433-bb1c-8f0cc18bba25'	System	14 Oct 2020 22:29:05
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 22:29:05

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:27:33', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a9689a3a-fc11-4433-bb1c-8f0cc18bba25'	System	14 Oct 2020 22:29:05
User entered 'No (N)'	System	14 Oct 2020 22:29:05

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:28:57', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a9689a3a-fc11-4433-bb1c-8f0cc18bba25'	System	14 Oct 2020 22:29:05
User entered 'No (N)'	System	14 Oct 2020 22:29:05

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:28:16', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a9689a3a-fc11-4433-bb1c-8f0cc18bba25'	System	14 Oct 2020 22:29:05
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 22:29:05

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:29:02', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a9689a3a-fc11-4433-bb1c-8f0cc18bba25'	System	14 Oct 2020 22:29:05
User entered '14 Oct 2020 17:29'	System	14 Oct 2020 22:29:05

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 4'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:04', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '653d0993-9f85-4642-83f6-71fcd9c839be' User entered 'None (1)'	System	16 Oct 2020 06:20:26
	System	16 Oct 2020 06:20:26

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:09', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '653d0993-9f85-4642-83f6-71fcd9c839be' User entered 'No (N)'	System	16 Oct 2020 06:20:26
	System	16 Oct 2020 06:20:26

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:15', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '653d0993-9f85-4642-83f6-71fcd9c839be' User entered 'No (N)'	System	16 Oct 2020 06:20:26
	System	16 Oct 2020 06:20:26

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:20', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '653d0993-9f85-4642-83f6-71fcd9c839be' User entered 'None (1)'	System	16 Oct 2020 06:20:26
	System	16 Oct 2020 06:20:26

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:23', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '653d0993-9f85-4642-83f6-71fcd9c839be' User entered '16 Oct 2020 01:20'	System	16 Oct 2020 06:20:26
	System	16 Oct 2020 06:20:26

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 5'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:44:59', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '19617fb7-4e66-413e-be26-7cec305c1a8c'	System	17 Oct 2020 04:45:14
User entered 'None (1)'	System	17 Oct 2020 04:45:14

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:45:02', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '19617fb7-4e66-413e-be26-7cec305c1a8c' User entered 'No (N)'	System	17 Oct 2020 04:45:14
	System	17 Oct 2020 04:45:14

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:45:05', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '19617fb7-4e66-413e-be26-7cec305c1a8c' User entered 'No (N)'	System	17 Oct 2020 04:45:14
	System	17 Oct 2020 04:45:14

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:45:08', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '19617fb7-4e66-413e-be26-7cec305c1a8c'	System	17 Oct 2020 04:45:14
User entered 'None (1)'	System	17 Oct 2020 04:45:14

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:45:11', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '19617fb7-4e66-413e-be26-7cec305c1a8c' User entered '16 Oct 2020 23:45'	System	17 Oct 2020 04:45:14
	System	17 Oct 2020 04:45:14

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 6'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:03:03', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '64f113be-8457-428f-9141-ca42ad29732b' User entered 'None (1)'	System	18 Oct 2020 04:03:17
	System	18 Oct 2020 04:03:17

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:03:06', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '64f113be-8457-428f-9141-ca42ad29732b' User entered 'No (N)'	System	18 Oct 2020 04:03:17
	System	18 Oct 2020 04:03:17

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:03:09', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '64f113be-8457-428f-9141-ca42ad29732b' User entered 'No (N)'	System	18 Oct 2020 04:03:17
	System	18 Oct 2020 04:03:17

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:03:12', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '64f113be-8457-428f-9141-ca42ad29732b' User entered 'None (1)'	System	18 Oct 2020 04:03:17
	System	18 Oct 2020 04:03:17

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:03:15', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '64f113be-8457-428f-9141-ca42ad29732b' User entered '17 Oct 2020 23:03'	System	18 Oct 2020 04:03:17
	System	18 Oct 2020 04:03:17

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 7'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:18', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f6882474-7bd7-4ff7-8dee-4e7b0ed49339'	System	19 Oct 2020 04:55:39
User entered 'None (1)'	System	19 Oct 2020 04:55:39

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:21', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f6882474-7bd7-4ff7-8dee-4e7b0ed49339' User entered 'No (N)'	System	19 Oct 2020 04:55:39
	System	19 Oct 2020 04:55:39

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:29', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f6882474-7bd7-4ff7-8dee-4e7b0ed49339' User entered 'No (N)'	System	19 Oct 2020 04:55:39
	System	19 Oct 2020 04:55:39

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

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 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:33', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f6882474-7bd7-4ff7-8dee-4e7b0ed49339'	System	19 Oct 2020 04:55:39
User entered 'None (1)'	System	19 Oct 2020 04:55:39

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:36', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f6882474-7bd7-4ff7-8dee-4e7b0ed49339' User entered '18 Oct 2020 23:55'	System	19 Oct 2020 04:55:39
	System	19 Oct 2020 04:55:39

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:01:59', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9d06bf9d-70d0-434e-a21b-7e124923260f' User entered 'None (0)'	System	12 Oct 2020 16:02:34
	System	12 Oct 2020 16:02:34

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:02:14', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9d06bf9d-70d0-434e-a21b-7e124923260f' User entered 'None (0)'	System	12 Oct 2020 16:02:34
	System	12 Oct 2020 16:02:34

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:02:17', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9d06bf9d-70d0-434e-a21b-7e124923260f' User entered 'None (0)'	System	12 Oct 2020 16:02:34
	System	12 Oct 2020 16:02:34

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:02:19', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9d06bf9d-70d0-434e-a21b-7e124923260f' User entered 'None (0)'	System	12 Oct 2020 16:02:34
	System	12 Oct 2020 16:02:34

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:02:22', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9d06bf9d-70d0-434e-a21b-7e124923260f' User entered 'None (0)'	System	12 Oct 2020 16:02:34
	System	12 Oct 2020 16:02:34

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:02:24', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9d06bf9d-70d0-434e-a21b-7e124923260f' User entered 'None (0)'	System	12 Oct 2020 16:02:34
	System	12 Oct 2020 16:02:34

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:02:28', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9d06bf9d-70d0-434e-a21b-7e124923260f' User entered 'No (N)'	System	12 Oct 2020 16:02:34
	System	12 Oct 2020 16:02:34

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T11:02:31', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9d06bf9d-70d0-434e-a21b-7e124923260f' User entered '12 Oct 2020 11:02'	System	12 Oct 2020 16:02:34
	System	12 Oct 2020 16:02:34

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '12 Oct 2020 10:53'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '12 Oct 2020 13:23'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 1, after vaccination (at home)'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:18:45', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '04b93af6-9062-43ba-a1fe-67f0d1b68880'	System	13 Oct 2020 01:19:14
User entered 'No interference with activity (1)'	System	13 Oct 2020 01:19:14

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:18:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '04b93af6-9062-43ba-a1fe-67f0d1b68880' User entered 'None (0)'	System	13 Oct 2020 01:19:14
	System	13 Oct 2020 01:19:14

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:18:52', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '04b93af6-9062-43ba-a1fe-67f0d1b68880' User entered 'None (0)'	System	13 Oct 2020 01:19:14
	System	13 Oct 2020 01:19:14

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:18:55', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '04b93af6-9062-43ba-a1fe-67f0d1b68880' User entered 'None (0)'	System	13 Oct 2020 01:19:14
	System	13 Oct 2020 01:19:14

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:18:58', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '04b93af6-9062-43ba-a1fe-67f0d1b68880' User entered 'None (0)'	System	13 Oct 2020 01:19:14
	System	13 Oct 2020 01:19:14

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:19:02', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '04b93af6-9062-43ba-a1fe-67f0d1b68880' User entered 'None (0)'	System	13 Oct 2020 01:19:14
	System	13 Oct 2020 01:19:14

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:19:08', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '04b93af6-9062-43ba-a1fe-67f0d1b68880' User entered 'No (N)'	System	13 Oct 2020 01:19:14
	System	13 Oct 2020 01:19:14

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-12T20:19:12', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '04b93af6-9062-43ba-a1fe-67f0d1b68880' User entered '12 Oct 2020 20:19'	System	13 Oct 2020 01:19:14
	System	13 Oct 2020 01:19:14

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '12 Oct 2020 14:18'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 2'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 15:38:40
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	02 Mar 2021 21:23:40
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site and Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise, please clarify.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 11:34:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:24', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ac72abef-1b95-46a4-9d3a-dba731482df5'	System	14 Oct 2020 03:11:02
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	14 Oct 2020 03:11:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:32', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ac72abef-1b95-46a4-9d3a-dba731482df5'	System	14 Oct 2020 03:11:02
User entered 'No interference with activity (1)'	System	14 Oct 2020 03:11:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:36', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ac72abef-1b95-46a4-9d3a-dba731482df5' User entered 'None (0)'	System	14 Oct 2020 03:11:02
	System	14 Oct 2020 03:11:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:40', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ac72abef-1b95-46a4-9d3a-dba731482df5' User entered 'None (0)'	System	14 Oct 2020 03:11:02
	System	14 Oct 2020 03:11:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:43', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ac72abef-1b95-46a4-9d3a-dba731482df5' User entered 'None (0)'	System	14 Oct 2020 03:11:02
	System	14 Oct 2020 03:11:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:45', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ac72abef-1b95-46a4-9d3a-dba731482df5' User entered 'None (0)'	System	14 Oct 2020 03:11:02
	System	14 Oct 2020 03:11:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

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)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ac72abef-1b95-46a4-9d3a-dba731482df5' User entered 'No (N)'	System	14 Oct 2020 03:11:02
	System	14 Oct 2020 03:11:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-13T22:10:57', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'ac72abef-1b95-46a4-9d3a-dba731482df5' User entered '13 Oct 2020 22:10'	System	14 Oct 2020 03:11:02
	System	14 Oct 2020 03:11:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '13 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '14 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 3'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:29:08', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f061d339-7332-4cd0-8fdc-e0f5ff1e82d9'	System	14 Oct 2020 22:29:45
User entered 'No interference with activity (1)'	System	14 Oct 2020 22:29:45

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:29:13', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f061d339-7332-4cd0-8fdc-e0f5ff1e82d9' User entered 'None (0)'	System	14 Oct 2020 22:29:45
	System	14 Oct 2020 22:29:45

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:29:19', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f061d339-7332-4cd0-8fdc-e0f5ff1e82d9' User entered 'None (0)'	System	14 Oct 2020 22:29:45
	System	14 Oct 2020 22:29:45

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:29:22', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f061d339-7332-4cd0-8fdc-e0f5ff1e82d9' User entered 'None (0)'	System	14 Oct 2020 22:29:45
	System	14 Oct 2020 22:29:45

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:29:29', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f061d339-7332-4cd0-8fdc-e0f5ff1e82d9' User entered 'None (0)'	System	14 Oct 2020 22:29:45
	System	14 Oct 2020 22:29:45

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:29:33', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f061d339-7332-4cd0-8fdc-e0f5ff1e82d9' User entered 'None (0)'	System	14 Oct 2020 22:29:45
	System	14 Oct 2020 22:29:45

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

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)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:29:37', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f061d339-7332-4cd0-8fdc-e0f5ff1e82d9' User entered 'No (N)'	System	14 Oct 2020 22:29:45
	System	14 Oct 2020 22:29:45

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-14T17:29:43', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'f061d339-7332-4cd0-8fdc-e0f5ff1e82d9' User entered '14 Oct 2020 17:29'	System	14 Oct 2020 22:29:45
	System	14 Oct 2020 22:29:45

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '14 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '15 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 4'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:30', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '068dad75-464b-45cc-8d84-7969b53a0b3a'	System	16 Oct 2020 06:20:57
User entered 'No interference with activity (1)'	System	16 Oct 2020 06:20:57

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:33', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '068dad75-464b-45cc-8d84-7969b53a0b3a' User entered 'None (0)'	System	16 Oct 2020 06:20:57
	System	16 Oct 2020 06:20:57

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:36', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '068dad75-464b-45cc-8d84-7969b53a0b3a' User entered 'None (0)'	System	16 Oct 2020 06:20:57
	System	16 Oct 2020 06:20:57

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:39', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '068dad75-464b-45cc-8d84-7969b53a0b3a' User entered 'None (0)'	System	16 Oct 2020 06:20:57
	System	16 Oct 2020 06:20:57

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:42', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '068dad75-464b-45cc-8d84-7969b53a0b3a' User entered 'None (0)'	System	16 Oct 2020 06:20:57
	System	16 Oct 2020 06:20:57

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:45', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '068dad75-464b-45cc-8d84-7969b53a0b3a' User entered 'None (0)'	System	16 Oct 2020 06:20:57
	System	16 Oct 2020 06:20:57

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

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)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:50', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '068dad75-464b-45cc-8d84-7969b53a0b3a' User entered 'No (N)'	System	16 Oct 2020 06:20:57
	System	16 Oct 2020 06:20:57

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T01:20:55', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '068dad75-464b-45cc-8d84-7969b53a0b3a' User entered '16 Oct 2020 01:20'	System	16 Oct 2020 06:20:57
	System	16 Oct 2020 06:20:57

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '15 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '16 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 5'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:44:27', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15599722-365f-45d2-8f55-48c25ef5e92c' User entered 'None (0)'	System	17 Oct 2020 04:44:54
	System	17 Oct 2020 04:44:54

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:44:30', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15599722-365f-45d2-8f55-48c25ef5e92c' User entered 'None (0)'	System	17 Oct 2020 04:44:54
	System	17 Oct 2020 04:44:54

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:44:33', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15599722-365f-45d2-8f55-48c25ef5e92c' User entered 'None (0)'	System	17 Oct 2020 04:44:54
	System	17 Oct 2020 04:44:54

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:44:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15599722-365f-45d2-8f55-48c25ef5e92c' User entered 'None (0)'	System	17 Oct 2020 04:44:54
	System	17 Oct 2020 04:44:54

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:44:38', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15599722-365f-45d2-8f55-48c25ef5e92c' User entered 'None (0)'	System	17 Oct 2020 04:44:54
	System	17 Oct 2020 04:44:54

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:44:41', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15599722-365f-45d2-8f55-48c25ef5e92c' User entered 'None (0)'	System	17 Oct 2020 04:44:54
	System	17 Oct 2020 04:44:54

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

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)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:44:45', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15599722-365f-45d2-8f55-48c25ef5e92c' User entered 'No (N)'	System	17 Oct 2020 04:44:54
	System	17 Oct 2020 04:44:54

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-16T23:44:48', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '15599722-365f-45d2-8f55-48c25ef5e92c' User entered '16 Oct 2020 23:44'	System	17 Oct 2020 04:44:54
	System	17 Oct 2020 04:44:54

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '16 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '17 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 6'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:02:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e49e56c0-3e3e-48f3-827b-95f5d093966a' User entered 'None (0)'	System	18 Oct 2020 04:02:56
	System	18 Oct 2020 04:02:56

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:02:37', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e49e56c0-3e3e-48f3-827b-95f5d093966a' User entered 'None (0)'	System	18 Oct 2020 04:02:56
	System	18 Oct 2020 04:02:56

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:02:39', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e49e56c0-3e3e-48f3-827b-95f5d093966a' User entered 'None (0)'	System	18 Oct 2020 04:02:56
	System	18 Oct 2020 04:02:56

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:02:41', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e49e56c0-3e3e-48f3-827b-95f5d093966a' User entered 'None (0)'	System	18 Oct 2020 04:02:56
	System	18 Oct 2020 04:02:56

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:02:43', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e49e56c0-3e3e-48f3-827b-95f5d093966a' User entered 'None (0)'	System	18 Oct 2020 04:02:56
	System	18 Oct 2020 04:02:56

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:02:45', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e49e56c0-3e3e-48f3-827b-95f5d093966a' User entered 'None (0)'	System	18 Oct 2020 04:02:56
	System	18 Oct 2020 04:02:56

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

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)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:02:48', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e49e56c0-3e3e-48f3-827b-95f5d093966a' User entered 'No (N)'	System	18 Oct 2020 04:02:56
	System	18 Oct 2020 04:02:56

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-17T23:02:52', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e49e56c0-3e3e-48f3-827b-95f5d093966a' User entered '17 Oct 2020 23:02'	System	18 Oct 2020 04:02:56
	System	18 Oct 2020 04:02:56

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '17 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '18 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
Data entry locked.	System	12 Oct 2020 15:35:02
User entered 'Day 7'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:43', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '42143e2e-d8fe-44d0-b7cf-4cbe66fbfdcc' User entered 'None (0)'	System	19 Oct 2020 04:56:06
	System	19 Oct 2020 04:56:06

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:46', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '42143e2e-d8fe-44d0-b7cf-4cbe66fbfdcc' User entered 'None (0)'	System	19 Oct 2020 04:56:06
	System	19 Oct 2020 04:56:06

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:48', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '42143e2e-d8fe-44d0-b7cf-4cbe66fbfdcc' User entered 'None (0)'	System	19 Oct 2020 04:56:06
	System	19 Oct 2020 04:56:06

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:50', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '42143e2e-d8fe-44d0-b7cf-4cbe66fbfdcc' User entered 'None (0)'	System	19 Oct 2020 04:56:06
	System	19 Oct 2020 04:56:06

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:53', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '42143e2e-d8fe-44d0-b7cf-4cbe66fbfdcc' User entered 'None (0)'	System	19 Oct 2020 04:56:06
	System	19 Oct 2020 04:56:06

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:55', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '42143e2e-d8fe-44d0-b7cf-4cbe66fbfdcc' User entered 'None (0)'	System	19 Oct 2020 04:56:06
	System	19 Oct 2020 04:56:06

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

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)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:55:58', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '42143e2e-d8fe-44d0-b7cf-4cbe66fbfdcc' User entered 'No (N)'	System	19 Oct 2020 04:56:06
	System	19 Oct 2020 04:56:06

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-10-18T23:56:01', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '42143e2e-d8fe-44d0-b7cf-4cbe66fbfdcc'	System	19 Oct 2020 04:56:06
User entered '18 Oct 2020 23:56'	System	19 Oct 2020 04:56:06

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '18 Oct 2020 12:00'	System	12 Oct 2020 15:35:02

US3392287

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:48:00
User entered '19 Oct 2020 11:59'	System	12 Oct 2020 15:35:02

US3392287

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:04:57
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	05 Nov 2020 19:03:30

US3392287

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:04:57
User entered '19 Oct 2020'	Heather Salisbury (b) (4)	05 Nov 2020 19:03:30

US3392287

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:04:57
User entered 'Contact Made (CONTACT MADE)'	Heather Salisbury (b) (4)	05 Nov 2020 19:03:30

US3392287

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:04:57
User entered empty.	Heather Salisbury (b) (4)	05 Nov 2020 19:03:30

US3392287

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:04:57
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	05 Nov 2020 19:03:34

US3392287

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'I'	System	05 Nov 2020 19:03:34

US3392287

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:48:33
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	05 Nov 2020 19:03:50

US3392287

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:48:33
User entered '26 Oct 2020'	Heather Salisbury (b) (4)	05 Nov 2020 19:03:50

US3392287

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:48:33
User entered 'Contact Made (CONTACT MADE)'	Heather Salisbury (b) (4)	05 Nov 2020 19:03:50

US3392287

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:48:33
User entered empty.	Heather Salisbury (b) (4)	05 Nov 2020 19:03:50

US3392287

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:48:33
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	05 Nov 2020 19:03:54

US3392287

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'I'	System	05 Nov 2020 19:03:54

US3392287

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:31:35
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	05 Nov 2020 19:04:08

US3392287

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:31:35
User entered '02 Nov 2020'	Heather Salisbury (b) (4)	05 Nov 2020 19:04:08

US3392287

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:31:35
User entered 'Contact Made (CONTACT MADE)'	Heather Salisbury (b) (4)	05 Nov 2020 19:04:08

US3392287

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:31:35
User entered empty.	Heather Salisbury (b) (4)	05 Nov 2020 19:04:08

US3392287

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:31:35
User entered 'Yes (Y)'	Heather Salisbury (b) (4)	05 Nov 2020 19:04:12

US3392287

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'I'	System	05 Nov 2020 19:04:12

US3392287

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:27

US3392287

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered '06 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:27

US3392287

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[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 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:27

US3392287

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'VISIT3'	System	06 Nov 2020 18:05:27

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	System	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	System	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	System	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	System	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered empty.	System	06 Nov 2020 18:05:33

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32

US3392287

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32

US3392287

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:38

US3392287

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:38

US3392287

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:57

US3392287

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Nov2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Nov2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' answered with 'UNSCHEDULED SAMPLE COLLECTED ON 06/NOV/2020 IS FOR VISIT 3 DAY 57.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 08:58:17
	(b) (4), (b) (6)	04 Jan 2021 22:54:40
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06Nov2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 23:31:54
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 18:05:57

US3392287

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered '10:30'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:57

US3392287

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered '06 Nov 2020 10:30'	System	06 Nov 2020 18:05:57

US3392287

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:30:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 18:05:43

US3392287

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'I'	System	06 Nov 2020 18:05:43

US3392287

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered 'Day 64'	System	16 Sep 2020 17:19:20

US3392287

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-16T01:20:50', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c3e14f67-404b-452b-93b0-24ac115a1a04' User entered 'No (N)'	System	16 Nov 2020 07:21:21
	System	16 Nov 2020 07:21:21

US3392287

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-16T01:21:11', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c3e14f67-404b-452b-93b0-24ac115a1a04'	System	16 Nov 2020 07:21:21
User entered 'No (N)'	System	16 Nov 2020 07:21:21

US3392287

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-16T01:21:19', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c3e14f67-404b-452b-93b0-24ac115a1a04' User entered '16 Nov 2020 01:21:19'	System	16 Nov 2020 07:21:21
	System	16 Nov 2020 07:21:21

US3392287

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered '16 Nov 2020 00:01'	System	16 Sep 2020 17:19:20

US3392287

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 03:03:44
Data entry locked.	System	16 Sep 2020 17:19:20
User entered '20 Nov 2020 23:59'	System	16 Sep 2020 17:19:20

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:24:02
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'NO MEDICALLY ATTENDED ADVERSE EVENT NOR ADVERSE EVENT TO BE CAPTURED FROM THE ENTRY MADE BY THE SUBJECT THAT WAS TRANSCRIBED ONTO THIS ECRF PAGE.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 22:53:14
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Dec 2020 09:20:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-23T00:18:35', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0948a9a3-6755-46f6-988a-bd9f44063b14'	System	23 Nov 2020 06:19:53
User entered 'Yes (Y)'	System	23 Nov 2020 06:19:53

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-23T00:18:46', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0948a9a3-6755-46f6-988a-bd9f44063b14' User entered 'No (N)'	System	23 Nov 2020 06:19:53
	System	23 Nov 2020 06:19:53

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-23T00:18:54', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0948a9a3-6755-46f6-988a-bd9f44063b14' User entered 'No (N)'	System	23 Nov 2020 06:19:53
	System	23 Nov 2020 06:19:53

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-23T00:19:08', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0948a9a3-6755-46f6-988a-bd9f44063b14' User entered 'Yes (Y)'	System	23 Nov 2020 06:19:53
	System	23 Nov 2020 06:19:53

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Please 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-23T00:19:22', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0948a9a3-6755-46f6-988a-bd9f44063b14'	System	23 Nov 2020 06:19:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 06:19:53

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-23T00:19:42', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '0948a9a3-6755-46f6-988a-bd9f44063b14' User entered '23 Nov 2020 00:19:42'	System	23 Nov 2020 06:19:53
	System	23 Nov 2020 06:19:53

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-27T00:01:19', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'cdb8b701-291e-4911-88dc-6a2c8d8a59e5'	System	27 Nov 2020 06:01:47
User entered 'No (N)'	System	27 Nov 2020 06:01:47

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-27T00:01:30', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'cdb8b701-291e-4911-88dc-6a2c8d8a59e5'	System	27 Nov 2020 06:01:47
User entered 'No (N)'	System	27 Nov 2020 06:01:47

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-11-27T00:01:36', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'cdb8b701-291e-4911-88dc-6a2c8d8a59e5' User entered '27 Nov 2020 00:01:36'	System	27 Nov 2020 06:01:47
	System	27 Nov 2020 06:01:47

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-04T00:18:04', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd377ab02-371c-4c86-ae3a-2a71cf92553a' User entered 'No (N)'	System	04 Dec 2020 06:18:20
	System	04 Dec 2020 06:18:20

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-04T00:18:12', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd377ab02-371c-4c86-ae3a-2a71cf92553a' User entered 'No (N)'	System	04 Dec 2020 06:18:20
	System	04 Dec 2020 06:18:20

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-04T00:18:17', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'd377ab02-371c-4c86-ae3a-2a71cf92553a' User entered '04 Dec 2020 00:18:17'	System	04 Dec 2020 06:18:20
	System	04 Dec 2020 06:18:20

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-11T00:01:30', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5d49e886-4cd2-4d41-96e9-884db0679f21' User entered 'No (N)'	System	11 Dec 2020 06:01:52
	System	11 Dec 2020 06:01:52

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-11T00:01:38', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5d49e886-4cd2-4d41-96e9-884db0679f21' User entered 'No (N)'	System	11 Dec 2020 06:01:52
	System	11 Dec 2020 06:01:52

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-11T00:01:43', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5d49e886-4cd2-4d41-96e9-884db0679f21' User entered '11 Dec 2020 00:01:43'	System	11 Dec 2020 06:01:52
	System	11 Dec 2020 06:01:52

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:43:40
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Not reportable per protocol' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 18:50:10
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:53:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-18T23:48:24', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e1690185-b21a-49a9-9028-1c9350859950'	System	19 Dec 2020 05:49:29
User entered 'Yes (Y)'	System	19 Dec 2020 05:49:29

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-18T23:48:40', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e1690185-b21a-49a9-9028-1c9350859950'	System	19 Dec 2020 05:49:29
User entered 'No (N)'	System	19 Dec 2020 05:49:29

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-18T23:48:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e1690185-b21a-49a9-9028-1c9350859950'	System	19 Dec 2020 05:49:29
User entered 'No (N)'	System	19 Dec 2020 05:49:29

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-18T23:48:58', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e1690185-b21a-49a9-9028-1c9350859950'	System	19 Dec 2020 05:49:29
User entered 'Yes (Y)'	System	19 Dec 2020 05:49:29

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Please 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-18T23:49:06', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e1690185-b21a-49a9-9028-1c9350859950'	System	19 Dec 2020 05:49:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Dec 2020 05:49:29

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-18T23:49:19', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e1690185-b21a-49a9-9028-1c9350859950'	System	19 Dec 2020 05:49:29
User entered '18 Dec 2020 23:49:19'	System	19 Dec 2020 05:49:29

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-25T11:33:19', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '501c91ca-2f6d-4e47-af71-42b6a198df32' User entered 'No (N)'	System	25 Dec 2020 17:33:51
	System	25 Dec 2020 17:33:51

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-25T11:33:39', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '501c91ca-2f6d-4e47-af71-42b6a198df32'	System	25 Dec 2020 17:33:51
User entered 'No (N)'	System	25 Dec 2020 17:33:51

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2020-12-25T11:33:49', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '501c91ca-2f6d-4e47-af71-42b6a198df32' User entered '25 Dec 2020 11:33:49'	System	25 Dec 2020 17:33:51
	System	25 Dec 2020 17:33:51

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-03T12:10:21', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '395913ba-e78d-403c-a6ae-5b710b251922'	System	03 Jan 2021 18:10:38
User entered 'No (N)'	System	03 Jan 2021 18:10:38

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-03T12:10:32', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '395913ba-e78d-403c-a6ae-5b710b251922'	System	03 Jan 2021 18:10:38
User entered 'No (N)'	System	03 Jan 2021 18:10:38

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-03T12:10:36', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '395913ba-e78d-403c-a6ae-5b710b251922' User entered '03 Jan 2021 12:10:36'	System	03 Jan 2021 18:10:38
	System	03 Jan 2021 18:10:38

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-08T00:06:50', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '69ebbc29-9303-4666-b5e2-5ea35043d824'	System	08 Jan 2021 06:07:15
User entered 'No (N)'	System	08 Jan 2021 06:07:15

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-08T00:07:05', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '69ebbc29-9303-4666-b5e2-5ea35043d824'	System	08 Jan 2021 06:07:15
User entered 'No (N)'	System	08 Jan 2021 06:07:15

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-08T00:07:11', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '69ebbc29-9303-4666-b5e2-5ea35043d824' User entered '08 Jan 2021 00:07:11'	System	08 Jan 2021 06:07:15
	System	08 Jan 2021 06:07:15

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-17T13:30:10', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'cc0fdb7d-754d-4089-8a3d-fedbe0308735'	System	17 Jan 2021 19:30:43
User entered 'No (N)'	System	17 Jan 2021 19:30:43

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-17T13:30:36', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'cc0fdb7d-754d-4089-8a3d-fedbe0308735'	System	17 Jan 2021 19:30:43
User entered 'No (N)'	System	17 Jan 2021 19:30:43

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-17T13:30:41', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'cc0fdb7d-754d-4089-8a3d-fedbe0308735' User entered '17 Jan 2021 13:30:41'	System	17 Jan 2021 19:30:43
	System	17 Jan 2021 19:30:43

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-22T00:47:38', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9badf052-f328-4c5d-9bc8-e20d3f4535a8'	System	22 Jan 2021 06:47:53
User entered 'No (N)'	System	22 Jan 2021 06:47:53

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-22T00:47:45', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9badf052-f328-4c5d-9bc8-e20d3f4535a8'	System	22 Jan 2021 06:47:53
User entered 'No (N)'	System	22 Jan 2021 06:47:53

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-22T00:47:50', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9badf052-f328-4c5d-9bc8-e20d3f4535a8' User entered '22 Jan 2021 00:47:50'	System	22 Jan 2021 06:47:53
	System	22 Jan 2021 06:47:53

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-29T00:48:57', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '4f39dcc3-1d7f-481c-9aef-6dc59584ffb5'	System	29 Jan 2021 06:49:16
User entered 'No (N)'	System	29 Jan 2021 06:49:16

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-29T00:49:05', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '4f39dcc3-1d7f-481c-9aef-6dc59584ffb5'	System	29 Jan 2021 06:49:16
User entered 'No (N)'	System	29 Jan 2021 06:49:16

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-01-29T00:49:09', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '4f39dcc3-1d7f-481c-9aef-6dc59584ffb5' User entered '29 Jan 2021 00:49:09'	System	29 Jan 2021 06:49:16
	System	29 Jan 2021 06:49:16

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-09T12:10:06', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '12fdc52a-860b-4a6f-a3e7-634050659634' User entered 'Yes (Y)'	System	09 Feb 2021 18:12:48
	System	09 Feb 2021 18:12:48

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-09T12:10:13', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '12fdc52a-860b-4a6f-a3e7-634050659634' User entered 'No (N)'	System	09 Feb 2021 18:12:48

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-09T12:10:21', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '12fdc52a-860b-4a6f-a3e7-634050659634' User entered 'No (N)'	System	09 Feb 2021 18:12:48

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-09T12:10:30', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '12fdc52a-860b-4a6f-a3e7-634050659634' User entered 'Yes (Y)'	System	09 Feb 2021 18:12:48
	System	09 Feb 2021 18:12:48

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Please 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-09T12:10:38', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '12fdc52a-860b-4a6f-a3e7-634050659634'	System	09 Feb 2021 18:12:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Feb 2021 18:12:48

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-09T12:10:52', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '12fdc52a-860b-4a6f-a3e7-634050659634' User entered '09 Feb 2021 12:10:52'	System	09 Feb 2021 18:12:48
	System	09 Feb 2021 18:12:48

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-14T12:00:53', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '8aa447aa-5b04-4d23-a6f4-70c44ca2ff6a' User entered 'No (N)'	System	14 Feb 2021 18:02:50
	System	14 Feb 2021 18:02:50

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-14T12:01:02', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '8aa447aa-5b04-4d23-a6f4-70c44ca2ff6a' User entered 'No (N)'	System	14 Feb 2021 18:02:50
	System	14 Feb 2021 18:02:50

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-14T12:01:06', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '8aa447aa-5b04-4d23-a6f4-70c44ca2ff6a' User entered '14 Feb 2021 12:01:06'	System	14 Feb 2021 18:02:50
	System	14 Feb 2021 18:02:50

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-21T12:01:08', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '152593e6-4ec1-46aa-bd75-7f70772fa9f3' User entered 'No (N)'	System	21 Feb 2021 18:03:47
	System	21 Feb 2021 18:03:47

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-21T12:01:18', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '152593e6-4ec1-46aa-bd75-7f70772fa9f3'	System	21 Feb 2021 18:03:47
User entered 'No (N)'	System	21 Feb 2021 18:03:47

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-21T12:01:23', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '152593e6-4ec1-46aa-bd75-7f70772fa9f3'	System	21 Feb 2021 18:03:47
User entered '21 Feb 2021 12:01:23'	System	21 Feb 2021 18:03:47

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-26T02:02:41-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c9ea11dc-352e-4aa7-a3b2-639f0375a187'	System	26 Feb 2021 08:03:27
User entered 'No (N)'	System	26 Feb 2021 08:03:27

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-26T02:03:18-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c9ea11dc-352e-4aa7-a3b2-639f0375a187'	System	26 Feb 2021 08:03:27
User entered 'No (N)'	System	26 Feb 2021 08:03:27

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-02-26T02:03:23-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'c9ea11dc-352e-4aa7-a3b2-639f0375a187'	System	26 Feb 2021 08:03:27
User entered '26 Feb 2021 08:03:23'	System	26 Feb 2021 08:03:27

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-05T09:01:13-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2f7e46e1-ae15-49b7-bba0-9603654cb4ed'	System	05 Mar 2021 15:01:30
User entered 'No (N)'	System	05 Mar 2021 15:01:30

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-05T09:01:23-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2f7e46e1-ae15-49b7-bba0-9603654cb4ed'	System	05 Mar 2021 15:01:30
User entered 'No (N)'	System	05 Mar 2021 15:01:30

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-05T09:01:27-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '2f7e46e1-ae15-49b7-bba0-9603654cb4ed' User entered '05 Mar 2021 09:01:27'	System	05 Mar 2021 15:01:30
	System	05 Mar 2021 15:01:30

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-12T09:01:23-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'aeff6b28-4e43-4b5c-9a43-0efdeb2225df' User entered 'No (N)'	System	12 Mar 2021 15:02:21
	System	12 Mar 2021 15:02:21

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-12T09:01:48-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'aeff6b28-4e43-4b5c-9a43-0efdeb2225df' User entered 'No (N)'	System	12 Mar 2021 15:02:21

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-12T09:02:18-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'aeff6b28-4e43-4b5c-9a43-0efdeb2225df' User entered '12 Mar 2021 09:02:18'	System	12 Mar 2021 15:02:21
	System	12 Mar 2021 15:02:21

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-22T01:50:36-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1c1dce6b-1620-4184-baba-05caf3b5bc72'	System	22 Mar 2021 06:50:55
User entered 'No (N)'	System	22 Mar 2021 06:50:55

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-22T01:50:40-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1c1dce6b-1620-4184-baba-05caf3b5bc72'	System	22 Mar 2021 06:50:55
User entered 'No (N)'	System	22 Mar 2021 06:50:55

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-22T01:50:53-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1c1dce6b-1620-4184-baba-05caf3b5bc72'	System	22 Mar 2021 06:50:55
User entered '22 Mar 2021 01:50:53'	System	22 Mar 2021 06:50:55

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-26T02:08:38-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1a1a6d02-be5a-4158-8709-aebde9339dc5'	System	26 Mar 2021 07:08:54
User entered 'No (N)'	System	26 Mar 2021 07:08:54

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-26T02:08:45-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1a1a6d02-be5a-4158-8709-aebde9339dc5'	System	26 Mar 2021 07:08:54
User entered 'No (N)'	System	26 Mar 2021 07:08:54

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-26T02:08:49-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '1a1a6d02-be5a-4158-8709-aebde9339dc5' User entered '26 Mar 2021 02:08:49'	System	26 Mar 2021 07:08:54
	System	26 Mar 2021 07:08:54

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-02T00:13:52-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e599781d-04ea-461a-8d97-a22a71f82eea' User entered 'No (N)'	System	02 Apr 2021 05:14:01
	System	02 Apr 2021 05:14:01

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-02T00:13:55-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e599781d-04ea-461a-8d97-a22a71f82eea' User entered 'No (N)'	System	02 Apr 2021 05:14:01

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-02T00:13:59-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'e599781d-04ea-461a-8d97-a22a71f82eea' User entered '02 Apr 2021 00:13:59'	System	02 Apr 2021 05:14:01
	System	02 Apr 2021 05:14:01

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-12T17:59:17-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a2afc1ba-6caa-45c1-9dd0-ce37a07a57f4'	System	12 Apr 2021 22:59:28
User entered 'No (N)'	System	12 Apr 2021 22:59:28

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-12T17:59:22-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a2afc1ba-6caa-45c1-9dd0-ce37a07a57f4'	System	12 Apr 2021 22:59:28
User entered 'No (N)'	System	12 Apr 2021 22:59:28

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-12T17:59:25-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: 'a2afc1ba-6caa-45c1-9dd0-ce37a07a57f4'	System	12 Apr 2021 22:59:28
User entered '12 Apr 2021 17:59:25'	System	12 Apr 2021 22:59:28

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-20T11:11:20-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9e36cf0e-d88f-47f7-92e3-577af3ab1c5c'	System	20 Apr 2021 16:13:30
User entered 'No (N)'	System	20 Apr 2021 16:13:30

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-20T11:11:24-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9e36cf0e-d88f-47f7-92e3-577af3ab1c5c'	System	20 Apr 2021 16:13:30
User entered 'No (N)'	System	20 Apr 2021 16:13:30

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-20T11:11:28-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '9e36cf0e-d88f-47f7-92e3-577af3ab1c5c'	System	20 Apr 2021 16:13:30
User entered '20 Apr 2021 11:11:28'	System	20 Apr 2021 16:13:30

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-26T18:15:36-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '601bf679-2d3e-4578-b89e-2e390dc4b26c'	System	26 Apr 2021 23:15:47
User entered 'No (N)'	System	26 Apr 2021 23:15:47

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-26T18:15:42-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '601bf679-2d3e-4578-b89e-2e390dc4b26c'	System	26 Apr 2021 23:15:47
User entered 'No (N)'	System	26 Apr 2021 23:15:47

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-26T18:15:45-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '601bf679-2d3e-4578-b89e-2e390dc4b26c' User entered '26 Apr 2021 18:15:45'	System	26 Apr 2021 23:15:47
	System	26 Apr 2021 23:15:47

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-30T00:10:29-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '85001740-4361-4cbf-92fa-e0fb22f77880'	System	30 Apr 2021 05:10:42
User entered 'No (N)'	System	30 Apr 2021 05:10:42

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Have you been exposed to someone with 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 (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-30T00:10:33-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '85001740-4361-4cbf-92fa-e0fb22f77880'	System	30 Apr 2021 05:10:42
User entered 'No (N)'	System	30 Apr 2021 05:10:42

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-04-30T00:10:37-05:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '85001740-4361-4cbf-92fa-e0fb22f77880'	System	30 Apr 2021 05:10:42
User entered '30 Apr 2021 00:10:37'	System	30 Apr 2021 05:10:42

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 08:55:49

US3392287

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:55:49
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 08:55:49

US3392287

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 07:49:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-05T09:01:49-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5ac7ab8b-b00e-400c-bac4-3ae5217e8da5'	System	05 Mar 2021 15:02:10
User entered 'No (N)'	System	05 Mar 2021 15:02:10

US3392287

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:22:36

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:49:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4809C6D2-40A2-4F9E-8E94-0BE01785EF15)', Time: '2021-03-05T09:02:07-06:00', User OID: 'PatientReportedOutcome (US3392287)', ODM File OID: '5ac7ab8b-b00e-400c-bac4-3ae5217e8da5' User entered '05 Mar 2021 09:02:07'	System	05 Mar 2021 15:02:10
	System	05 Mar 2021 15:02:10

US3392287

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 23:04:41
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Dec 2020 22:22:19

US3392287

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 23:04:41
User entered '04 Dec 2020'	Brenda Lawson (b) (4)	28 Dec 2020 22:22:19

US3392287

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 23:04:41
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	28 Dec 2020 22:22:19

US3392287

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 23:04:41
User entered empty.	Brenda Lawson (b) (4)	28 Dec 2020 22:22:19

US3392287

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 23:04:41
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Dec 2020 22:22:36

US3392287

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:05:32
User entered 'I'	System	28 Dec 2020 22:22:36

US3392287

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Dec 2020 22:23:29
	(b) (4)	

US3392287

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '28 Dec 2020'	Brenda Lawson (b) (4)	28 Dec 2020 22:23:29
	(b) (4)	

US3392287

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	28 Dec 2020 22:23:29
	(b) (4)	

US3392287

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered empty.	Brenda Lawson (b) (4)	28 Dec 2020 22:23:29
	(b) (4)	

US3392287

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:16
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Dec 2020 22:23:34
	(b) (4)	

US3392287

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:05:16
User entered 'I'	System	28 Dec 2020 22:23:34

US3392287

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 22:06:08

US3392287

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '9 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 22:06:08

US3392287

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Feb 2021 22:06:08

US3392287

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 22:06:08

US3392287

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:27
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 22:06:11

US3392287

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:41:27
User entered 'I'	System	10 Feb 2021 22:06:11

US3392287

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:39
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:46:25

US3392287

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:39
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '12 Mar 2021'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:46:25

US3392287

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:39
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:46:25

US3392287

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:39
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:46:25

US3392287

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:39
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Mar 2021 21:46:29

US3392287

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:36:39
User entered 'I'	System	12 Mar 2021 21:46:29

US3392287

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:09

US3392287

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:09

US3392287

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:09

US3392287

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	29 Mar 2021 19:27:09

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 19:27:13

US3392287

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:17

US3392287

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:17

US3392287

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:28

US3392287

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:28

US3392287

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '13:30'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:28

US3392287

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User entered '29 Mar 2021 13:30'	System	29 Mar 2021 19:27:28

US3392287

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:27:31

US3392287

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 19:27:31

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:22:36

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:39:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 15:38:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Jan 2021 13:41:10
Query 'Data is required. Please complete.' answered with 'Data entry error - this subject should not have covid-19 assessment' (Site from System).	Brandon Illickal (b) (4)	26 Jan 2021 00:57:55
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:57:28
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	26 Jan 2021 00:57:28
User entered '21 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 22:22:26

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:22:36

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:39:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 15:38:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Jan 2021 13:41:13
Query 'Data is required. Please complete.' answered with 'Data entry error - this subject should not have covid-19 assessment' (Site from System).	Brandon Illickal (b) (4)	26 Jan 2021 00:57:57
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:57:28
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	26 Jan 2021 00:57:28
User entered '14:25'	(b) (4), (b) (6)	22 Dec 2020 22:22:26

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:22:36

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	27 Jan 2021 15:39:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 15:38:17
User entered empty.	System	26 Jan 2021 00:57:28
User entered '21 Dec 2020 14:25'	System	22 Dec 2020 22:22:26

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:22:36

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:39:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 15:38:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Jan 2021 13:41:15
Query 'Data is required. Please complete.' answered with 'Data entry error - this subject should not have covid-19 assessment' (Site from System).	Brandon Illickal (b) (4)	26 Jan 2021 00:57:59
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:57:28
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	26 Jan 2021 00:57:28
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	22 Dec 2020 22:22:26

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Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:22:36

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:39:08
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	27 Jan 2021 15:38:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Jan 2021 13:41:17
Query 'Data is required. Please complete.' answered with 'Data entry error - this subject should not have covid-19 assessment' (Site from System).	Brandon Illickal (b) (4)	26 Jan 2021 00:58:01
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 00:57:28
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	26 Jan 2021 00:57:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 22:22:26

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '99'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User entered '%'	System	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

US3392287

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:22:36

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:23:08

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:22:36

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:51:10
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4)	26 Jan 2021 00:52:35
	Brandon Illickal (b) (4)	

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:28:11

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:28:11

US3392287

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:28:11

US3392287

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

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 20:28:11

US3392287

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:38:57

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 21:45:26
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:09:57

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:38:57

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 15:31:15
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:45:32
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 21:45:26
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:01:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:09:57

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:38:57

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:38:57

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 04:48:40
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 20:38:57

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 04:48:40
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	15 Jan 2021 20:38:57

US3392287

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:38:57

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User entered empty.	System	15 Jan 2021 20:38:57

US3392287

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

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User entered empty.	System	15 Jan 2021 20:38:57

US3392287

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:39:19

US3392287

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:39:19

US3392287

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '11:58'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:39:19

US3392287

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User entered '15 Jan 2021 11:58'	System	15 Jan 2021 20:39:19

US3392287

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:39:39

US3392287

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '15 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:39:39

US3392287

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '12:00'	(b) (4) (b) (4), (b) (6)	15 Jan 2021 20:39:39

US3392287

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:41
User entered '15 Jan 2021 12:00'	System	15 Jan 2021 20:39:39

US3392287

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:22:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 68 & 96, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 14:43:59
Query 'Per DM CLR: Per Safety Follow Up Diary Day 68 & 96, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'No reportable per protocol' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:03:58
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 68 & 96, 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 17:19:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	09 Feb 2021 18:33:29

US3392287

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:22:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 01:09:09

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:02:07
User entered 'USA-US119-2021-mRNA-1273-P301000005'	System	10 Feb 2021 17:05:42
User entered 'New'	(b) (4), (b) (6)	10 Feb 2021 17:05:42

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation aggravated - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Feb 2021 15:38:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 15:38:57
Data point term sent to Coder	System	09 Feb 2021 18:47:24
User entered 'Worsening chronic Atrial fibrillation'	Brandon Illickal (b) (4) (b) (4) (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '08 Feb 2021'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '09 Feb 2021'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:38:36
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 15:38:34
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:02:37
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Medical records have been sent to Moderna' (Site from Safety).	Brandon Illickal (b) (4)	28 Apr 2021 20:51:44
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:34:23
User entered 'I'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '08 Feb 2021'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '09 Feb 2021'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'I'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '1'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 15:02:22
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Medical records have been sent to Moderna' (Site from Safety).	Brandon Illickal (b) (4)	28 Apr 2021 20:51:31
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:33:46
User entered 'subject was admitted to the hospital overnight with worsening atrial fibrillation. subject was treated with ablation and sotalol.'	Brandon Illickal (b) (4)	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 18:46:48

US3392287

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 18:46:48

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:22:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:54:22

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 23:49:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 23:49:26
Data point term sent to Coder	System	06 Nov 2020 20:55:39
User entered 'DULOXENTINE'	(b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'DEPRESSION'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '60'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:57:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'UN Jan 2000'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 20:57:25
User entered '1'	System	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:55:12

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS IC, PRODUCT: FLECAINIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 21:13:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:13:28
Data point term sent to Coder	System	06 Nov 2020 20:57:40
User entered 'FLECAINIDE'	(b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'ATRIAL FIBRILLATION'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '100'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 20:57:33
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'UN Jan 2007'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 20:57:33
User entered '1'	System	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:56:43

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Nov 2020 21:29:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:29:23
Data point term sent to Coder	System	06 Nov 2020 20:57:41
User entered 'METOPROLOL'	(b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'ATRIAL FIBRILLATION'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '25'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'UN Sep 2019'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:57:18

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 21:00:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 21:00:32
Data point term sent to Coder	System	06 Nov 2020 20:59:43
User entered 'rivaroxaban'	(b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'ATRIAL FIBRILLATION'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '20'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'UN Mar 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Nov 2020 20:58:47

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Nov 2020 21:01:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 21:01:29
Data point term sent to Coder	System	06 Nov 2020 21:00:45
User entered 'TRAZADONE'	(b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'DEPRESSION'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '50'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'UN Jan 2019'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:00:13

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
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)	03 Mar 2021 13:45:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 13:45:58
Data point term sent to Coder	System	02 Mar 2021 21:26:58
User entered 'TYLENOL [acetaminophen]' reason for change: Data Entry Error	Brandon Illickal (b) (4)	02 Mar 2021 21:26:30
Data point term sent to Coder	System	02 Mar 2021 21:25:56
Data point term sent to Coder	System	02 Mar 2021 21:24:55
Coding entries removed.	Brandon Illickal (b) (4)	02 Mar 2021 21:24:02
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)	09 Feb 2021 18:34:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:34:34
Data point term sent to Coder	System	09 Feb 2021 18:33:12
Coding entries removed.	Brandon Illickal (b) (4)	09 Feb 2021 18:32:15
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)	05 Jan 2021 03:10:51

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Jan 2021 03:10:51
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	05 Jan 2021 03:09:58
User entered 'tylenol'	Brandon Illickal (b) (4)	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4)	05 Jan 2021 03:09:26
	Brandon Illickal (b) (4)	

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
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 HEADACHE, PAIN AT INJECTION SITE are 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 HEADACHE, PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 08:06:49
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE, PAIN AT INJECTION SITE are 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 HEADACHE, PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' answered with 'indication does not meet AE criteria.' (Site from DM).	Brandon Illickal (b) (4)	12 Mar 2021 21:00:05

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[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 HEADACHE, PAIN AT INJECTION SITE are 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 HEADACHE, PAIN AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 20:00:21
User closed query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 15:39:16
Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' answered with 'data entry error. Subject incorrectly entered data on temperature diary. subject took acetaminophen for heache and injection site pain on 13OCT2020' (Site from DM).	Brandon Illickal (b) (4)	02 Mar 2021 21:26:18
User entered 'headache, PAIN AT INJECTION SITE' reason for change: Data Entry Error	Brandon Illickal (b) (4)	02 Mar 2021 21:25:31
User entered 'FEVER, pain at injection site' reason for change: Data Entry Error	Brandon Illickal (b) (4)	02 Mar 2021 21:24:02
User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:38:36

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User entered 'Fever' reason for change: Data Entry Error	Brandon Illickal (b) (4)	09 Feb 2021 18:32:15
User entered 'body aches'	Brandon Illickal (b) (4)	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '1000'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'mg (mg)'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4)	05 Jan 2021 03:09:26
	Brandon Illickal (b) (4)	

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'once daily (QD)'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4)	05 Jan 2021 03:09:26
	Brandon Illickal (b) (4)	

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Oral (ORAL)'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered empty.	(b) (4)	05 Jan 2021 03:09:26
	Brandon Illickal (b) (4)	

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Brandon Illickal (b) (4)	09 Feb 2021 18:33:03
User entered '12 Oct 2020'	(b) (4)	
	Brandon Illickal (b) (4)	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '0'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'No (N)'	(b) (4)	05 Jan 2021 03:09:26
	Brandon Illickal (b) (4)	

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	02 Mar 2021 21:25:31
User entered '18 Oct 2020' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	09 Feb 2021 18:33:03
User entered '17 Oct 2020'	(b) (4) Brandon Illickal (b) (4)	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User closed query 'Per DM CLR-RQ: Response noted. However, there is also no record of FEVER in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 15:39:27
Query 'Per DM CLR-RQ: Response noted. However, there is also no record of FEVER in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' answered with 'data has been corrected.' (Site from DM).	Brandon Illickal (b) (4)	02 Mar 2021 21:26:38
User opened query 'Per DM CLR-RQ: Response noted. However, there is also no record of FEVER in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:39:26
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of BODY ACHES in eDiary. Please note that this CM was given at Day 1 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 14:56:52

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of BODY ACHES in eDiary. Please note that this CM was given at Day 1 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' answered with 'indication is fever. data has been corrected' (Site from DM). User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of BODY ACHES in eDiary. Please note that this CM was given at Day 1 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRFupdate this field to No. Else, provide clarification.' (Site from DM). User entered 'Yes (Y)'	Brandon Illickal (b) (4) (b) (4), (b) (6)	09 Feb 2021 18:32:40 09 Feb 2021 14:58:03 05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User entered '1'	System	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User entered '1'	System	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:39:52
User entered '804 (804)'	System	05 Jan 2021 03:09:26

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, NON-SELECTIVE, PRODUCT: SOTALOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Feb 2021 11:50:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 11:50:04
Data point term sent to Coder	System	09 Feb 2021 18:50:26
User entered 'sotalol'	Brandon Illickal (b) (4) (b) (4) (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'worsening chronic atrial fibrillation'	(b) (4) Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '60'	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'mg (mg)'	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'twice daily (BID)'	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '08 Feb 2021'	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '0'	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 13:53:45
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'This is new daily medication the patient was started on due to AE event. Field is accurate. ' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 16:47:37
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:37:31
User entered empty.	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'No (N)'	Brandon Illickal (b) (4)	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Feb 2021 18:49:30

US3392287

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:22:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:25:21
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Brandon Illickal (b) (4)	09 Feb 2021 18:49:46
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 01:09:13

US3392287

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered '08 Feb 2021'	Brandon Illickal (b) (4)	09 Feb 2021 18:50:04

US3392287

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'cardiac ablation'	Brandon Illickal (b) (4)	09 Feb 2021 18:50:04

US3392287

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered 'Adverse Event (AE)'	Brandon Illickal (b) (4)	09 Feb 2021 18:50:04

US3392287

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
	(b) (4)	
User entered empty.	Brandon Illickal (b) (4)	09 Feb 2021 18:50:04

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'USA-US119-2021-MRNA-1273-P301000005'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'Yes (Y)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'No (N)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'No (N)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'Yes (Y)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'No (N)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'No (N)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'No (N)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'Michael'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'Cotugno'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'US'	(b) (4) System	10 Feb 2021 17:06:51

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Feb 2021 17:06:51

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'USA-US119-2021-MRNA-1273-P301000005'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'Yes (Y)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'No (N)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'No (N)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'Yes (Y)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'No (N)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'No (N)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'No (N)'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'Michael'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:02
User entered 'Cotugno'	System	10 Feb 2021 17:05:42

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'US'	(b) (4) System	10 Feb 2021 17:06:51

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Feb 2021 17:06:51

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:22:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered '10/Feb/2021 11:06'	(b) (4) System	10 Feb 2021 17:06:51

US3392287

Folder: SAE USA-US119-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:22:36

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:10:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 17:06:51